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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

THE PONCA TRIBE OF INDIANS OF
OKLAHOMA

Plaintiff,

vs.

MCKINSEY & CO., INC.; MCKINSEY
HOLDINGS, INC.; MCKINSEY &
COMPANY, INC. UNITED STATES;
MCKINSEY & COMPANY, INC.
WASHINGTON D.C.; PUBLICIS HEALTH,
LLC; PRACTICE FUSION, INC.;
ALLSCRIPTS HEALTHCARE
SOLUTIONS, INC.; and ZS ASSOCIATES,
INC.

Defendants.

Case No. 21-md-02996-CRB (SK)

ORIGINAL COMPLAINT

REDACTED FOR PUBLIC FILING

JURY TRIAL DEMANDED

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I. INTRODUCTION

1. For two decades now, the modern¹ opioid crisis has raged. In 2017, the President of the United States announced a public health emergency. In 2020, drug-overdose deaths in the United States soared nearly 30%.² Drug overdoses now kill more than 100,000 Americans per year – more than vehicle crash and gun deaths combined.³ Today, there are fewer and fewer Americans whose lives have not been scarred by the epidemic.

2. History repeats itself not through accident or accretion, but through affirmative acts undertaken by those who wish it so. The modern epidemic has a cause, and this complaint seeks to hold accountable principal participants in its creation and propagation. The modern epidemic began with the introduction and expansive promotion of OxyContin by Purdue Pharma in 1996 and was driven thereafter by industry-wide marketing efforts in which Defendants were principal and knowing participants. It continues to rage today, further enflamed by the isolation of the COVID-19 pandemic.⁴

3. The pharmaceutical industry is complex and highly regulated. Drug manufacturers cannot, and do not, do everything on their own. These innovative companies endeavor to research,

¹ Throughout history, instances of widespread availability of opioids causing severe detriment to all of us are legion. To begin with, the drug was powerful enough to be used as a means of colonial expansion by the British Empire in China. There were two Opium Wars. *See* W. Travis Hanes III & Frank Sanello, *The Opium Wars: The Addiction of One Empire and the Corruption of Another*, 2002; Julia Lovell, *The Opium War: Drugs, Dreams, and the Making of Modern China*, 2011.

More recently, the United States has experienced previous waves of opioid abuse. “The first was in the early 1900’s, when heroin was marketed alongside Bayer aspirin as a remedy for numerous minor ailments.” Dr. Anna Lembke, *Drug Dealer, M.D.*, Johns Hopkins University Press (2016), Pg. 57. A second heroin epidemic struck the United States during the Vietnam War. *Id.* *See also* John Fauber et al., “A Look Back: Abandoned Painkiller Makes a Comeback,” *Medpage Today*, June 9, 2017, available at: <https://www.medpagetoday.com/psychiatry/addictions/65916> (describing the removal of Numorphan, an oxymorphone product, from the market in the 1970’s in response to widespread abuse). Throughout the time-period relevant to this complaint, the dangers of widespread opioid availability weren’t just common knowledge, they were historical fact.

² Betsy McKay, “U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids,” *Wall Street Journal*, July 14, 2020, available at: <https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200>

³ German Lopez, “A Rising Death Toll,” *New York Times*, February 13, 2022, available at: <https://www.nytimes.com/2022/02/13/briefing/opioids-drug-overdose-death-toll.html>.

⁴ <https://healthmatters.nyp.org/an-overdose-epidemic-amid-the-pandemic/>

1 develop, obtain approval, and bring to market products that improve the health and livelihood of
2 hundreds of millions of people worldwide. Because the scale of the industry is vast, the stakes –
3 both in terms of potential profit and impact on human lives – are high, and the industry’s complexity
4 byzantine. From cutting-edge medical and scientific research, to navigating the state and federal
5 regulatory environment, to marketing their drugs in a responsible manner to prescribers and the
6 consuming public, the demands on a traditional pharmaceutical manufacturer are multi-faceted,
7 ever-present, and continuously changing.

9 4. The reality is pharmaceutical manufacturers routinely rely on third parties to design,
10 implement, and oversee projects and workflows to achieve mission-critical tasks. Given the
11 complexity of the industry, there are numerous companies that find their niche in offering core
12 services to pharmaceutical manufacturers that are critical to the success of the manufacturers’
13 operations but are not performed by the manufacturer alone. These third parties are necessary
14 components of the drug manufacturing and sales industry as a whole.

16 5. Manufacturers do not rely on these third-party providers on a one-off basis, but
17 instead rely on companies like McKinsey, Publicis, ZS, and Practice Fusion again and again to
18 design and implement measures to achieve specific needs. The relationships are recurring and long-
19 term. It is not uncommon for McKinsey or ZS or Publicis to advise multiple pharmaceutical
20 manufacturers regarding the sales and marketing of competing products, such as branded extended-
21 release opioids. Further, it is common for third-party consultants such McKinsey, ZS and Publicis
22 to commoditize their business intelligence in a way which expands markets across the industry. In
23 other words, they often sell the same strategy to multiple clients. This complaint concerns the
24 conduct of these providers.

26 6. One Defendant – McKinsey – is the preeminent management consultancy on Earth.
27 Another – Publicis – is one of the largest advertising agencies on Earth. Publicis Groupe S.A. is the
28

1 French parent of Defendant Publicis Health LLC (“Publicis”). A third Defendant is a little known,
2 but principal architect of the sales and marketing efforts that begat the opioid crisis, pharmaceutical
3 consulting firm ZS Associates, Inc. (“ZS”). A fourth, Practice Fusion, Inc. (“Practice Fusion”)
4 offered a unique channel through which the marketing messages and strategy created by co-
5 Defendants could be delivered to the intended audience: healthcare providers, the folks with
6 prescription pads in their hands. All were crucial components of and contributors to the architecture
7 and functioning of the opioid marketplace.⁵

9 7. McKinsey is a management consulting firm with operations across the globe. It
10 played a central role in the unfolding, propagation, and exploitation of the opioid crisis by advising
11 multiple opioid manufacturers and other industry participants how to sell as many opioids as
12 conceivably possible. Knowing that its clients’ products were highly addictive, ineffective, and
13 unsafe for the treatment of long-term chronic pain, non-acute pain, and non-cancer pain, McKinsey
14 developed a singular focus on increasing opioid sales, no matter the resultant cost to society.
15 McKinsey did this for well over a decade, despite knowing full well the risk to public health and
16 safety and the widespread economic harm from developing and implementing the transformation
17 of strictly controlled substances into top-selling blockbuster drugs.

19 8. The purpose of McKinsey’s work with its opioids clients was at all times to
20 maximize return on investment. The whole point for those clients (and hence McKinsey) was to
21 make as much money as possible. They all did. This relentless drive to increase sales and create
22 greater availability of opioids was made with no concern about the parallel, known, and inevitable
23 increase in opioid-related deaths, addiction, abuse, diversion, and misuse.

25 9. In the world of management consulting, McKinsey is preeminent. It is one of the
26 world’s oldest, largest, and most lucrative consulting firms and is generally seen as the most
27

28 ⁵ The fifth defendant, Allscripts, Inc. (“Allscripts”) is the parent company of defendant Practice Fusion.

1 prestigious firm in the industry. More consiglieri than one-off advisor, McKinsey touts its model
 2 of engaging in “transformational partnerships” with its clients. McKinsey learns each client’s
 3 business intimately, embeds itself into all levels of the corporate hierarchy, and provides granular
 4 strategies to achieve transformative goals for its clients.

5
 6 10. Marvin Bower, the managing director of McKinsey from 1950 to 1967, was “the
 7 father of the consulting profession.”⁶ He “turned the business of selling management advice into a
 8 keystone of American corporate culture,” and is “credited with taking a fledgling industry and
 9 setting its course not only as to the kinds of services it could sell but also the standards it must
 10 uphold for its work to be respected.”⁷ A lawyer by trade, Bower stressed that management
 11 consulting should be seen as an emergent profession, akin to the law or accounting, with obligations
 12 to clients and to the broader society that extend beyond the mere commercial.

13
 14 11. Bower instilled an ethos at McKinsey that has been reinforced throughout the
 15 decades as a core value of the firm: “Deliver the bad news if you must, but deliver it properly.”⁸
 16 Bower’s principles, and the values he imparted within McKinsey, are said to guide the firm to the
 17 present day. “In many ways, certainly in spirit and soul, Marvin continued to lead it after he retired,
 18 and he leads it still,” eulogized Rajat Gupta, McKinsey’s then-global managing partner, at Bower’s
 19 funeral in 2003.⁹

21
 22 ⁶ Douglas Martin, *Marvin Bower*, 99; *Built McKinsey & Co.*, N.Y. Times, Jan. 24, 2003, available at:
<https://www.nytimes.com/2003/01/24/business/marvin-bower-99-built-mckinsey-co.html>

23 ⁷ *Id.*

24 ⁸ Duff McDonald, *The Firm* 35 (2014).

25 ⁹ *Id.* at 270. In many ways, Gupta was an interesting figure to opine on Bower’s legacy. Indeed, Gupta’s leadership of
 26 McKinsey is in many respects to be *contrasted* with Bower’s legacy. Many of the values Bower emphasized—an
 27 emphasis on professionalism over commercial exploitation, for example—were jettisoned under Gupta’s tenure as
 managing partner of the firm, which ended in 2003. “Under his watch, McKinsey began to chase top billings in a way
 it never had before.” *Id.* at 234. For instance, McKinsey first began accepting equity stakes in clients as a form of
 incentive compensation during Gupta’s tenure. Previously, McKinsey only charged standard fees for its consulting
 services as Bower disdained the notion of taking equity stakes in clients. *Id.* at 234. Under Gupta, McKinsey also began
 to allow consultants’ compensation to be tied to client performance. *Id.*

28 Consistent with Gupta’s efforts to monetize McKinsey’s consulting business in ways previous firm leadership
 had not, McKinsey also began to expand its client base. “While the firm would never admit as much, under Gupta,
 McKinsey began working for just about anyone with a fat bank account and a checkbook.” *Id.* at 266.

12. This case is, in large part, about the firm’s failure to adhere to Bower’s simple, foundational tenet. It arises instead from the firm’s steadfast and continual work to maximize opioid sales in partnership with numerous clients during the pendency of the worst man-made epidemic in modern medical history. It is about McKinsey never delivering the “bad news” of opioids’ devastating impact on Plaintiff and the public, and instead looking the other way for money.

13. When it came to opioids, McKinsey did far more than just give advice. Not only did it suggest courses of action that its clients should adopt, the firm remained in place and worked collaboratively alongside its clients to actually implement McKinsey’s recommendations to achieve objectives jointly identified by the clients and McKinsey. McKinsey stood alongside its clients in the arena doing the deeds.

14. The deceptive marketing strategies that McKinsey and its clients invented, developed, deployed, and continually refined for years to expand the market for opioids are foundational to the epidemic.

15. McKinsey worked hand-in-hand with major opioid manufacturers, including Purdue Pharma L.P., Endo Pharmaceuticals,¹⁰ Johnson & Johnson,¹¹ and Mallinckrodt¹² for years. At the same time, McKinsey advised other participants in the opioid supply chain, including distributors, pharmacies, and even regulators.

Institutions age, and by the time Gupta came to lead the firm in 1994, McKinsey was a mature institution. It had built up significant value in its *reputation* by historically advising *only* “blue chip” companies “at the top of the corporate pyramid.” *Id.* Under Gupta, McKinsey began the process of realizing that value. For McKinsey, the way to monetize an elite reputation was to start advising those it historically may have shunned as clients—to start offering its *imprimatur*, in addition to its services, for money. McKinsey’s work with opioid manufacturers began under Gupta’s leadership.

¹⁰ “Endo Pharmaceuticals” or “Endo” refers to Endo Health Solutions Inc., Endo International plc, and Endo Pharmaceuticals Inc., collectively.

¹¹ “Johnson & Johnson” refers to Johnson & Johnson Services, Inc. and its wholly-owned subsidiary Janssen Pharmaceuticals, Inc. (“Janssen”).

¹² “Mallinckrodt” refers to Mallinckrodt LLC and Mallinckrodt plc, together.

1 16. In particular, McKinsey advised the Sackler family and their company, Purdue, for
2 years while Purdue aggressively marketed OxyContin, widely viewed as the taproot of the opioid
3 crisis. The relationship began no later than 2004. In the years following Purdue's 2007 guilty plea
4 for misleadingly marketing OxyContin, McKinsey continued to work closely with Purdue to
5 dramatically increase OxyContin sales, notwithstanding the existence of a five-year Corporate
6 Integrity Agreement that Purdue entered as part of its guilty plea.
7

8 17. McKinsey knew of the dangers of opioids and in particular the prior misconduct of
9 Purdue but nonetheless advised Purdue and other opioid manufacturers to improperly market and
10 sell OxyContin and other prescription opioids, supplying granular sales and marketing strategies
11 and remaining intimately involved throughout implementation of those strategies. McKinsey's
12 actions resulted in a surge in sales of OxyContin and other opioids that fueled and prolonged the
13 opioid crisis.
14

15 18. For years, McKinsey advised Purdue on, designed, and helped to implement various
16 strategies to raise sales of OxyContin by focusing on high dose sales and deceptively messaging to
17 physicians that OxyContin would improve function and quality of life. For example, McKinsey
18 urged Purdue to maximize sales by dictating, to a greater degree, which prescribers its sales
19 representatives would target, exploring ways to increase the amount of time those sales
20 representatives spent in the field increasing opioid sales and prioritizing OxyContin in incentive
21 compensation targets.¹³
22

23 19. McKinsey's partnership with Purdue reached its fever pitch in the summer of 2013.
24 In January of that year, Purdue's Corporate Integrity Agreement expired, and Purdue was no longer
25 bound by its constraints. Within months, the Sacklers tasked McKinsey with transforming Purdue's
26
27
28

¹³ PPLPC012000437346

1 approach to OxyContin sales in order to extract as much money as possible from the remaining
 2 patent life of the drug.¹⁴

3 20. In response, McKinsey developed and proposed Project Turbocharge, a series of
 4 transformational changes that McKinsey proposed to implement at Purdue to dramatically increase
 5 OxyContin sales by re-tooling Purdue's sales force and investing large amounts of capital to
 6 "turbocharge" it. "[O]ur recommendation is that Purdue makes a clear go-no-go decision to
 7 'Turbocharge the Sales Engine'," McKinsey told Purdue on August 8, 2013.

9 21. The Sacklers chose "go," and McKinsey subsequently implemented and continually
 10 refined Project Turbocharge at Purdue over the course of years, to devastating, but profitable, effect.

11 22. McKinsey has recently been the subject of scrutiny for its various business practices,
 12 including its work facilitating the opioid crisis with Purdue.¹⁵ On March 7, 2019, Kevin Sneader,
 13 McKinsey's then-global managing partner, addressed all McKinsey employees regarding this
 14 scrutiny. Drawing inspiration from Theodore Roosevelt, Sneader stated,
 15

16 [W]e cannot return to a time when we were in the background and unobserved.
 17 Those days have gone. Indeed, I have little doubt that scrutiny—fair and unfair—
 18 will continue. It is the price we pay for being "in the arena" and working on what
 matters.¹⁶

19 ¹⁴ OxyContin, like any branded pharmaceutical, is subject to eventual patent expiration and competition from generic
 opioid manufacturers.

20 ¹⁵ See Michael Forsythe and Walt Bogdanich, *McKinsey Advised Purdue Pharma How to 'Turbocharge' Opioid Sales,*
Lawsuit Says, N.Y. Times, Feb. 1, 2019, available at: [https://www.nytimes.com/2019/02/01/business/purdue-pharma-](https://www.nytimes.com/2019/02/01/business/purdue-pharma-mckinsey-oxycontin-opioids.html)
 21 [mckinsey-oxycontin-opioids.html](https://www.nytimes.com/2019/02/01/business/purdue-pharma-mckinsey-oxycontin-opioids.html).

22 ¹⁶ See "The Price We Pay for Being 'In the Arena'": McKinsey's Chief Writes to Staff About Media Scrutiny and
Scandal, Fortune Magazine, March 8, 2019, available at [https://fortune.com/2019/03/08/mckinsey-staff-letter-kevin-](https://fortune.com/2019/03/08/mckinsey-staff-letter-kevin-sneader/)
 23 [sneader/](https://fortune.com/2019/03/08/mckinsey-staff-letter-kevin-sneader/). The "arena" reference is to *Citizenship in a Republic*, a speech delivered by Theodore Roosevelt at the
Sorbonne on April 23, 1910:

24 It is not the critic who counts; not the man who points out how the strong man stumbles, or where
 25 the doers of deeds could have done them better. The credit belongs to the man who is actually in the
 26 arena [here, McKinsey; and the arena, opioid sales], whose face is marred by dust and sweat and
 27 blood; who strives valiantly; who errs, who comes short again and again, because there is no effort
 28 without error and shortcoming; but who does actually strive to do the deeds; who knows great
 enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in
 the end the triumph of high achievement, and who at the worst, if he fails, at least fails while daring
 greatly, so that his place shall never be with those cold and timid souls who neither know victory
 nor defeat.

As it happens, Mr. Sneader is not the only McKinsey person to draw inspiration from Roosevelt. *Citizenship*
in a Republic similarly inspired Dominic Barton, the man Mr. Sneader succeeded as McKinsey's global managing

1 23. Weeks later, McKinsey announced that it would no longer work for any opioid
2 manufacturer. “Opioid abuse and addiction are having a tragic and devastating impact on our
3 communities. We are no longer advising clients on any opioid-specific business and are continuing
4 to support key stakeholders working to combat the crisis.”¹⁷

5 24. The price for being in the arena is more than mere scrutiny. McKinsey is liable for
6 its misconduct and the harms it caused or exacerbated. McKinsey is liable for its successful efforts
7 to increase opioid sales for years. It continued this work unabated and with alacrity despite events
8 as stunning as Purdue’s 2007 guilty plea for misbranding OxyContin, Purdue’s 2015 settlement
9 with the State of Kentucky, and numerous other enforcement actions related to opioid sales and
10 marketing by McKinsey clients. Through it all, McKinsey remained steadfast in its efforts to
11 promote opioid sales for all of its clients for the purpose of maximizing return on investment
12 without regard to the obvious implications of what they were doing. Indeed, the firm endeavored
13 alongside its clients to increase the size of the *overall* opioid market for *nearly two decades*, until
14 as late as March 22, 2019, despite increasingly blood-red flags along the way.¹⁸

15 25. And McKinsey was not alone; Defendants Publicis, ZS, and Practice Fusion
16 endeavored alongside McKinsey, shoulder to shoulder and in common cause with McKinsey and
17 their manufacturer clients to perpetuate and increase in size the opioids market; to sell more and
18 more pills.
19
20
21

22
23
24 partner. It served as the basis for his 2017 address to the Ivey Business School in Canada. *See* Dominic Barton *In the*
25 *Arena: Leadership in an Age of Disruption*, October 17, 2017, *available at*: https://www.ivey.uwo.ca/media/3780710/daquino_lecture2017.pdf. While McKinsey continues to preach the values of corporate integrity from the Bower area,
26 its actions show that that professed moral compass needs to be serviced; it doesn’t work anymore.

27 ¹⁷ *See* Paul La Monica, *Consulting firm McKinsey no longer working with opioid maker Purdue Pharma*, CNN, May
28 24, 2019, *available at*: <https://www.cnn.com/2019/05/24/business/mckinsey-purdue-pharma-oxycontin/index.html>.
The statement was attributed to McKinsey as an entity. No individual’s name was attributed.

¹⁸ *See* “About McKinsey’s past work for opioid manufacturers,” *last updated March 22, 2021*, *available at*:
<https://www.mckinseyopioidfacts.com> (“We decided nearly two years ago to end all work on opioid-specific
business”)

1 26. Publicis is one of the “Big Four,” the four firms that account for more than half of
 2 the global advertising industry. In 2002, as the opioid crisis was taking root across the United States,
 3 the president of the American Association of Advertising Agencies, stated, “Now you have four
 4 megacompanies with revenues that are staggering, bigger than some of the companies they serve.”¹⁹
 5 The rise of the Big Four came through decades of mergers and acquisitions of separate agencies;
 6 each is essentially a conglomerate. By October of 2021, Publicis had risen to become the largest
 7 advertising conglomerate in the world, with a market capitalization in excess of \$16 billion.²⁰

9 27. Publicis has acquired and developed particular expertise in serving the
 10 pharmaceutical industry. Publicis – through its’s myriad divisions – serves multiple pharmaceutical
 11 manufacturers in advertising their drugs. It relies on the healthcare sector for approximately 13%
 12 of its annual revenue, making it one of the largest industry sectors by revenue for the
 13 conglomerate.²¹

15 28. The over-marketing of opioids – schedule II controlled substances that are
 16 *controlled* because they are known to be addictive and deadly – was the wellspring of our national
 17 crisis. Although the introduction of OxyContin by Purdue Pharma L.P. (“Purdue”) in the late 1990’s
 18 is widely acknowledged as a precipitating cause of the opioid crisis, Purdue was not the only
 19 pharmaceutical company to enthusiastically foment and exploit the booming market of controlled
 20 substances used for the treatment of pain. An industry-wide sales and marketing effort was
 21 deployed over the years by numerous manufacturers of opioid medications in order to maximize
 22 the amount of opioids they could sell.

24 29. The sales and marketing efforts to sell opioids to as many individuals as possible,
 25 even when they were known to be addictive, were not solely designed by the manufacturers
 26

27 ¹⁹ Stuart Elliott, Advertising’s Big Four: It’s Their World Now, *New York Times*, March 31, 2002, available at:
 28 <https://www.nytimes.com/2002/03/31/business/advertising-s-big-four-it-s-their-world-now.html>

²⁰ See <https://www.prweek.com/article/1731568/publicis-overtakes-rivals-worlds-valuable-agency-group>

²¹ See <http://documents.publicisgroupe.com/resultat2021/Presentation-H1-2021-RESULTS.pdf> at 15.

1 themselves, nor did the manufacturers implement these tactics on their own. Rather, pharmaceutical
2 manufacturers routinely relied on Defendants to design and implement crucial aspects of the sales
3 and marketing strategies used to sell opioids.

4 30. Publicis did not produce mere copy. Publicis not only designed these sales and
5 marketing campaigns for numerous opioid manufacturers, it also worked in identifying the optimal
6 targets for the different messages Publicis delivered on behalf of its clients. In many instances,
7 pharmaceutical manufacturers would outsource practically the entire business of selling its drugs.
8 Through Publicis Touchpoint Solutions, Publicis provided entire sales forces on a contract basis to
9 be used by their manufacturer clients to detail prescribers.

11 31. Nor was Publicis merely some ancillary vendor. Because of its partnerships with
12 multiple clients selling competing branded opioid products contemporaneously, Publicis's role was
13 unique. It served as a hub, aggregating knowledge of what numerous competitors within the
14 industry were doing with respect to designing sales and marketing campaigns, contemporaneously.
15 Indeed, Publicis worked with industry-wide groups to address challenges that the entire opioids
16 industry faced and compiled invaluable insights and business intelligence which it commoditized
17 by providing it to numerous clients.

19 32. As a hub, Publicis also connected opioid manufacturers to specialist vendors, such
20 as Defendant Practice Fusion, who worked with Publicis and Purdue to target and deliver content
21 to healthcare providers designed to increase the amount of Purdue's opioids sold through Practice
22 Fusion's proprietary software platform used in doctors' offices across the country.

24 33. ZS is a private consulting company that specializes in the pharmaceutical industry.
25 It was founded in 1983 by two professors at the eminent Kellogg School of Business at
26 Northwestern University. Since then, ZS has achieved substantial growth, and now employs
27 thousands of consultants and enjoys hundreds of millions of dollars in annual revenue. "ZS" is the
28

1 initials of the two founders, Professors Andris Zoltners and Prabhakant Sinha. In 2020 ZS had 8,000
2 employees and was listed as one the Best Management Consulting Firms by Forbes in 2021.²²

3 34. In particular, ZS specializes in providing critical pharmaceutical sales and marketing
4 services to drive increased sales volume and related profits.

5 35. As set forth in this complaint, Defendants' purpose in working with these companies
6 was plain and singular: to maximize profits for their clients by making sure that every dollar spent
7 on sales and marketing of opioids generated as many sales of these addictive controlled substances
8 as possible. Maximizing profits and revenue for Defendants' clients was achieved by maximizing
9 the total volume of opioids sold. McKinsey, Publicis and ZS applied their sales and marketing
10 acumen to multiple opioid brands on behalf of numerous manufacturer clients, and often at the
11 same time. McKinsey, Publicis and ZS were common denominators throughout.

12 36. These Defendants played a central role in the creation, prolongation, and
13 exploitation of the opioid crisis for money. As the alarm bells sounded repeatedly in the early years
14 of the unfolding crisis, Defendants – like McKinsey – continued their work with opioid
15 manufacturers unabated and with alacrity, and for decades, as the bells rose to cacophony. It
16 continued right up until the bitter end.²³

17 37. Moreover, the work was conducted in the shadows. Defendants treat their client
18 relationships as confidential. Classically, ZS or Publicis – like McKinsey - works behind the scenes
19 and does not publicize its work. Until recent consultant litigation, the public had essentially no
20 knowledge or awareness of the extent of involvement that Defendants – like McKinsey – had in
21 tearing apart our social fabric for profit. The Ponca Tribe, with its eyes now fully open to the true
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27 ²² See <https://www.forbes.com/companies/zs/?sh=12e5e93027d0>

28 ²³ For instance, ZS had an active contract with Purdue Pharma L.P. ("Purdue") to assist with the sales and marketing of OxyContin in 2018, after Purdue had already pled guilty, settled numerous prior lawsuits brought by the DOJ, state Attorneys General and individuals and faced a new wave of similar litigation. That year, with its contract with ZS still active, Purdue chose to disband its sales force and cease marketing the drug altogether.

1 scope of the origins and prolongation of the opioid crisis, seek to hold all those responsible
2 accountable.

3 **II. JURISDICTION AND VENUE**

4 38. Plaintiff brings this action by filing directly in in the Northern District of California
5 pursuant to Paragraph 10 of this Court's Case Management Order Dated November 20, 2121 (Doc.
6 #293). Plaintiff reserves the right to have this matter transferred to the United States District Court
7 in which it would have originally filed this case absent consolidation, the United States District
8 Court for the Northern District of Oklahoma.

10 39. The United States District Court for the Northern District of Oklahoma has subject
11 matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because (i) at least one
12 member of the putative Class is a citizen of a state different from Defendants (ii) the amount in
13 controversy exceeds \$5,000,000, exclusive of interest and costs, and (iii) none of the exceptions
14 under the subsection apply to this action.

16 40. The United States District Court for the Northern District of Oklahoma has personal
17 jurisdiction over the Defendants because Plaintiffs claims arise out of, or relate to, Defendants'
18 contacts with Oklahoma.

19 41. The United States District Court for the Northern District of Oklahoma has personal
20 jurisdiction over the Defendants because Plaintiffs claims arise out of, or relate to, Defendant's
21 contacts with Oklahoma.

23 42. At all times relevant hereto, Defendants engaged in the business of researching,
24 designing, and implementing sales and marketing strategies for various opioid manufacturers
25 including Purdue Pharma in the State of Oklahoma and Oklahoma County and the territorial limits
26 of the Ponca Tribe of Indians of Oklahoma.

1 43. The United States District Court for the Western District of Oklahoma has
2 jurisdiction over Defendants due to Defendant's conduct in Oklahoma County and throughout
3 Oklahoma. Defendants have deliberately engaged in significant acts and omissions within State of
4 Oklahoma and Oklahoma County and the territorial limits of the Ponca Tribe of Indians of
5 Oklahoma that have injured Plaintiff's residents. Defendants purposefully directed their activities
6 in State of Oklahoma and Oklahoma County and the territorial limits of the Ponca Tribe of Indians
7 of Oklahoma and its residents, and the claims arise out of those activities.

9 44. Venue is proper in the United States District Court for the Western District of
10 Oklahoma because a substantial part of the events giving rise to Plaintiff's claims occurred in, were
11 directed to, and/or emanated from this District. 28 U.S.C. § 1391(b).

12 **III. PARTIES**

13 45. Plaintiff Ponca Tribe of Indians of Oklahoma is a sovereign Indian Tribe recognized
14 by federal, state, and tribal law. The Ponca Tribe's jurisdictional territory encompasses Oklahoma
15 County, Oklahoma. Plaintiff is not a citizen of any state for purposes of diversity jurisdiction.

16 46. The Ponca Tribe exercises inherent and constitutional governmental authority on
17 behalf of the Tribe itself and its members. The Ponca Tribe brings this action on its own behalf and
18 on behalf of its members and citizens in the public interest to protect the health, safety, and welfare
19 of the citizens of the Ponca Tribe. The Ponca Tribe does so in an effort to address the opioid
20 addiction epidemic within the Ponca Tribe and to recover damages and seek other redress for the
21 harms cause by Defendant's conduct.

22 47. Defendant McKinsey & Company, Inc. is a corporation organized under the laws of
23 the state of New York. McKinsey's principal place of business is located at 711 Third Avenue,
24 New York, NY 10017. It may be served with process via its registered agent, Corporation Service
25 Company, at 80 State Street, Albany, NY 12207.

1 48. Defendant McKinsey Holdings, Inc. is a Delaware corporation with its principal
2 place of business is located at 711 Third Avenue, New York, NY 10017. It may be served with
3 process via its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington,
4 DE 19808

5 49. Defendant McKinsey & Company, Inc. United States is a Delaware corporation with
6 its principal place of business is located at 711 Third Avenue, New York, NY 10017. It may be
7 served with process via its registered agent, Corporation Service Company, 251 Little Falls Drive,
8 Wilmington, DE 19808

9 50. Defendant McKinsey & Company, Inc. Washington D.C. is a Delaware corporation
10 with its principal place of business is located at 711 Third Avenue, New York, NY 10017. It may
11 be served with process via its registered agent, Corporation Service Company, 251 Little Falls
12 Drive, Wilmington, DE 19808.

13 51. Upon information and belief, McKinsey & Company, Inc. is the parent company of
14 McKinsey & Company Holdings, Inc., which is itself the parent company of both McKinsey &
15 Company, Inc. United States and McKinsey & Company, Inc. Washington D.C. Upon information
16 and belief, each subsidiary corporation is wholly-owned by its parent. Despite the corporate form,
17 McKinsey began as a partnership and still refers to its senior employees as “partners.” Those
18 partners are the firm’s shareholders. Collectively, these four Defendants are referenced throughout
19 as “McKinsey.”

20 52. McKinsey a is global management consultancy with offices in over 130 cities in 65
21 countries, including the following United States cities: Atlanta, GA; Austin, TX; Houston, TX;
22 Dallas, TX; San Francisco, CA; Los Angeles, CA; Redwood City, CA; Boston, MA; Charlotte,
23 NC; Chicago, IL; Cleveland, OH; Denver, CO; Detroit, MI; Miami, FL; Miramar, FL; Tampa, FL;
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1 Minneapolis, MN; Summit, NJ; New York, NY; Philadelphia, PA; Pittsburgh, PA; Seattle, WA;
 2 St. Louis, MO; Stamford, CT; Waltham, MA; and Washington, D.C.

3 53. McKinsey is registered to do business in all fifty states.

4 54. Defendant Publicis Health, LLC (“Publicis Health”) is a Delaware limited liability
 5 company with its principal place of business in New York City. Additionally, Publicis maintains
 6 an office within the State at 100 E Penn Square, 11th Floor, Philadelphia, PA 19107, and is
 7 registered to do business in Pennsylvania. It may be served with process through its registered
 8 agent, Corporation Service Company, 2595 Interstate Dr. #103, Harrisburg, PA 17110.

9 55. Defendant Practice Fusion, Inc. (“Practice Fusion”) is a Delaware corporation with
 10 its headquarters in San Francisco, California. It may be served with process through its registered
 11 agent, National Registered Agents, Inc. located at 818 West Seventh St., Ste 930, Los Angeles, CA
 12 90017. Practice Fusion provided electronic health records (“EHR”) services to clinicians and
 13 healthcare providers, and was ultimately acquired by Defendant Allscripts.

14 56. Defendant Allscripts Healthcare Solutions, Inc. (“Allscripts”) is a Delaware
 15 corporation with its headquarters in Chicago, Illinois. On February 13, 2018, Allscripts completed
 16 a merger whereby it acquired Defendant Practice Fusion and became a successor in interest thereto.

17 57. Defendant ZS Associates, Inc., is a foreign corporation with its principal office
 18 located at 1800 Sherman Avenue, Evanston, Illinois 60201. It may be served with process through
 19 its registered agent, Illinois Service Corporation, 801 Adlai Stevenson Dr., Springfield, IL 62703.

20 **IV. FACTUAL ALLEGATIONS**

21 58. Organizationally, this complaint will tell the individual stories of each defendant,
 22 beginning with McKinsey, then Publicis, then Practice Fusion, and finally ZS, and will detail each
 23 defendant’s interactions with multiple opioid manufacturers – and each other – in turn. As will be
 24 seen, each worked for the same opioid manufacturers at the same time and on the same projects,
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1 and all were unified in their common purpose²⁴: to maximize opioid sales and associated profits for
2 the past two decades.

3 **a. The Opioid Crisis**

4 59. The term “opioid” refers to a class of drugs that bind with opioid receptors in the
5 brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from
6 the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body,
7 the most significant of which are analgesia, euphoria, and respiratory depression.

8 60. The opium poppy contains various opium alkaloids, three of which are used in the
9 pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western
10 medicine was a tincture of opium and alcohol called laudanum, which contains all of the opium
11 alkaloids and is still available by prescription today. Chemists first isolated the morphine and
12 codeine alkaloids in the early 1800s.

13 61. In 1827, the pharmaceutical company Merck began large-scale production and
14 commercial marketing of morphine. During the American Civil War, field medics commonly used
15 morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with
16 morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United
17 States, and many doctors prescribed opioids solely to prevent their patients from suffering
18 withdrawal symptoms. The nation’s first Opium Commissioner, Hamilton Wright, remarked in
19 1911: “The habit has this nation in its grip to an astonishing extent . . . Our prisons and our hospitals
20 are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them
21 beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness
22 and sin in the United States.”

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28 ²⁴ See “McKinsey on Implementation”, McKinsey & Company Inc., April 30, 2017, *available at*:
<https://www.youtube.com/watch?v=rEQOGVpl9CY> (“One thing intriguing about the engagements is that they often
have a common purpose, and a genuine cause,” Josh, a Senior Implementation Coach at McKinsey, explained.)

1 62. Pharmaceutical companies have long tried to develop substitutes for opium and
2 morphine that would provide the same analgesic effects without the addictive properties. In 1898,
3 Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of
4 morphine) under the trade name “Heroin.” Bayer advertised heroin as a non-addictive cough and
5 cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in
6 the United States was limited to prescription only in 1914 and then banned altogether a decade
7 later.
8

9 63. Although heroin and opium became classified as illicit drugs, there is little
10 difference between them and prescription opioids. Prescription opioids are synthesized from the
11 same plant as heroin, have similar molecular structures, and bind to the same receptors in the human
12 brain.
13

14 64. Due to concerns about their addictive properties, prescription opioids have usually
15 been regulated at the federal level as Schedule II controlled substances by the Drug Enforcement
16 Administration since 1970.

17 65. Throughout the twentieth century, pharmaceutical companies continued to develop
18 prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally
19 produced in combination with other drugs, with relatively low opioid content.
20

21 66. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern
22 opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths:
23 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers
24 as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times
25 that.
26

27 67. The effects of opioids vary by duration. Long-acting opioids, such as Purdue’s
28 OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s

1 Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid
2 therapy for, in general, twelve hours. Short-acting opioids, such as Cephalon's Actiq and Fentora,
3 are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred
4 to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting
5 approximately four to six hours. Still other short-term opioids, such as Insys's Subsys, are designed
6 to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain,
7 excruciating pain suffered by some patients with end-stage cancer. The opioid manufacturers
8 promoted the idea that pain should be treated by taking long-acting opioids continuously and
9 supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough"
10 pain.
11

12 68. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As
13 tolerance increases, a patient typically requires progressively higher doses in order to obtain the
14 same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the
15 "high." However, opioids depress respiration and, at very high doses, can, and often do, arrest
16 respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid
17 use can also cause hyperalgesia, a heightened sensitivity to pain.
18

19 69. Discontinuing opioids after more than just a few weeks of therapy will cause most
20 patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety,
21 nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other
22 serious symptoms, which may persist for months after a complete withdrawal from opioids,
23 depending on how long the opioids were used.
24

25 70. As one doctor put it, the widespread long-term use of opioids "was an experiment
26 on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was
27 collected until they started gathering death statistics."
28

71. The results were devastating, and the nation continues to reach ever grimmer milestones. In 2020, drug-overdose deaths in the United States soared nearly 30%, reaching all-time highs.²⁵

b. Selling Controlled Substances: Marketing and the Origins of the Opioid Crisis

72. Selling drugs is big business:

Perhaps the most powerful tool that pharmaceutical companies have for driving up profit margins and cultivating growth of drug markets is advertising. Pharmaceutical companies, especially the makers of opioid prescriptions, spend an enormous amount of money advertising their products – far more than they ever spend on drug research and development (Swanson 2015). In 2012 alone, the US pharmaceutical industry spent more than \$27 billion on drug promotion – including more than \$24 billion on marketing directly to physicians and \$3 billion advertising to consumers.²⁶

73. Professor Amanda Pustilnik of the Center for Law, Brain, & Behavior, and herself a former McKinsey & Company management consultant, emphasized the centrality of the role coordinated opioid sales and marketing played in creating the opioid crisis. “[T]he story of the opioid epidemic is often misrepresented as a story of irresponsible patients and over-prescribing doctors.” Referring to the recent lawsuit brought by the State of Massachusetts against Publicis, Professor Pustilnik identified a more pernicious cause: the efforts by defendants to change prescriber behavior: “[T]his prosecution gets at the heart of the matter. Patients and doctors were

²⁵ Betsy McKay, “U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids,” *Wall Street Journal*, July 14, 2020, available at: <https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200>.

²⁶ Melina Sherman, “Opiates for the masses: constructing a market for prescription (pain)killers,” *Journal of Cultural Economy*, Vol. 10, Issue 6, 2017, available at: <https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010> (citing Swanson, Ana, 2015. Big pharmaceutical companies are spending far more on marketing than on research. *The Washington Post*, February 11, available at: <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/>; Cegedim Strategic Data, 2013. *2012 U.S. pharmaceutical company promotion spending*. In the Pew Charitable Trust (2013), *Fact Sheet: Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, available at: <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients>).

1 not, on average, irresponsible. They acted under the influence of a concerted plan of misinformation
2 and over-promotion orchestrated up and down the supply chain for these medications.”²⁷

3 74. Defendants, including Professor Pustilnik’s former employer, were members of the
4 concert and enterprise that devised and executed the plan Pustilnik identified as a primary source
5 of the opioid crisis.
6

7 75. Although the introduction of OxyContin by Purdue Pharma in the late 1990’s is
8 widely acknowledged as a precipitating cause of the opioid crisis, Purdue was not the only
9 pharmaceutical company to enthusiastically foment and exploit the booming market of controlled
10 substances used for the treatment of pain. An industry-wide sales and marketing effort was
11 deployed over the years by numerous manufacturers of opioid medications in order to maximize
12 the amount of opioids they could sell.
13

14 76. As referenced above, OxyContin, the principal product of the Sackler family’s
15 Purdue Pharma L.P., was introduced to the market in 1996. Within six years of its introduction, the
16 increasingly widespread misuse and abuse of OxyContin and similar opioids had drawn the
17 attention of the United States Senate.
18

19 77. Two decades ago, Dr. Art Van Zee traveled from the rural coal town of St. Charles,
20 in the southwestern corner of Virginia, to Washington D.C. to provide testimony to the United
21 States Senate Committee on Health, Education, Labor and Pensions. On February 12, 2002, that
22 Committee held a hearing entitled “Examining the Effects of the Painkiller OxyContin, Focusing
23 on Federal, State, and Local Efforts to Decrease Abuse and Misuse of this Product While Assuring
24 Availability for Patients Who Suffer Daily from Chronic Moderate to Severe Pain.”²⁸
25
26

27 ²⁷ Thomas F. Harrison, “Novel Opioid Lawsuit Goes After Ad Agency,” Courthouse News, May 6, 2021, *available at*:
<https://www.courthousenews.com/novel-opioid-lawsuit-goes-after-ad-agency/>.

28 ²⁸ A transcript of the hearing is *available at*: <https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm>

1 78. In those early days of the unfolding opioid epidemic, Dr. Van Zee's medical practice
2 in St. Charles put him in a position to offer informed, first-hand observations of the toll that the
3 pharmaceutical industry's efforts to market opioids was exacting from his community. He testified:

4 In the 25 years I have practiced as a general internist in St. Charles, which is a small
5 Appalachian coal mining town, there has never been anything to compare to the
6 epidemic of drug abuse and addiction that we have seen the last 3 years with
7 OxyContin. Contrary to what is sometimes portrayed in the media as long-term
8 addicts switching to the drug *du jour*, what we have seen for the most part is
9 numerous young people recreationally using OxyContin and then becoming very
10 rapidly addicted. Many of these kids are good kids, good families with bright,
11 promising futures that are being destroyed in every way by their opioid addiction.²⁹

12 79. Further, Dr. Van Zee identified the sales and marketing practices of the
13 pharmaceutical industry when selling controlled substances as a primary cause of the problem:

14 My own personal view of the complicated OxyContin abuse problem is that there
15 are at least three major elements involved. First, there has been an obvious problem
16 with physician misprescribing and overprescribing of this drug. Second, this
17 epidemic has been a vicious indicator of the alarming degree of prescription drug
18 abuse in our society. **Third and perhaps the one closest to this committee and
19 the FDA is that the promotion and marketing of OxyContin by Purdue Pharma
20 has played a major role in this problem.**³⁰

21 80. Five years after Dr. Van Zee's testimony and 80 miles from his hometown of St.
22 Charles, United States Attorney John Brownlee announced in Abingdon, Virginia, the guilty plea
23 of the Purdue Frederick Company, the parent of Purdue Pharma, L.P., relating to the misbranding
24 of OxyContin. Brownlee stated, "Even in the face of warnings from health care professionals, the
25 media, and members of its own sales force that OxyContin was being widely abused and causing
26 harm to our citizens, Purdue, under the leadership of its top executives, continued to push a
27 fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse,
28 and less likely to cause withdrawal. In the process, scores died as a result of OxyContin abuse and
an even greater number of people became addicted to OxyContin; a drug that Purdue led many to

²⁹ See <https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm>

³⁰ *Id.* (emphasis added).

1 believe was safer, less subject to abuse, and less addictive than other pain medications on the
2 market.”³¹

3 81. Along with the guilty plea, Purdue agreed to a Corporate Integrity Agreement with
4 the Office of Inspector General of the United States Department of Health and Human Services.
5 For a period of five years, ending in 2012, Purdue was obligated to retain an Independent Monitor
6 and submit annual compliance reports regarding its marketing and sales practices and training of
7 sales representatives vis-à-vis their interactions with health care providers.
8

9 82. Two years later, in 2009, Dr. Van Zee published *The Promotion and Marketing of*
10 *OxyContin: Commercial Triumph, Public Health Tragedy* in the American Journal of Public
11 Health. As the title suggests, the paper applied formal rigor to some of the personal observations
12 Dr. Van Zee previously provided to the US Senate in 2002.
13

14 83. In his 2009 paper, Dr. Van Zee stated the matter plainly: “Compared with
15 noncontrolled drugs, controlled drugs, with their potential for abuse and diversion, pose different
16 public health risks when they are overpromoted and highly prescribed.”³² In one sense, Dr. Van
17 Zee’s observation is not particularly novel. Indeed, it approaches tautology: controlled substances
18 are *controlled* precisely because they should not be sold to maximize volume and profits. This did
19 not prevent Purdue and ZS from marketing its opioids full hilt, however. By 2004, “OxyContin had
20 become the most prevalent prescription opioid in the United States.”³³
21

22 84. Dr. Van Zee identified the three principal marketing tactics Purdue employed as a
23 source of OxyContin misuse and abuse and suggested that regulation may be appropriate to curtail
24

25
26 ³¹ See the May 10, 2007, News Release from United States Attorney, John Brownlee at
https://media.defense.gov/2007/May/10/2001711223/-1/-1/1/purdue_frederick_1.pdf

27 ³² Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, American
28 Journal of Public Health, February 2009, available at
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf>

³³ *Id.*

1 its use. The first was the use of granular sales and marketing data to profile individual prescribers
2 to identify those that already prescribe large amounts of opioids. “Through these profiles, a drug
3 company can identify the highest and lowest prescribers of particular drugs in a single zip code,
4 county, state, or the entire country. One of the critical foundations of Purdue’s marketing plan for
5 OxyContin was to target the physicians who were the highest prescribers for opioids across the
6 country.”³⁴

8 85. The second tactic was the use of incentive compensation structures to encourage the
9 salesforce to sell ever more prescriptions of OxyContin. Bonuses at Purdue were “uncapped,”
10 meaning there was no upper limit to what an OxyContin salesperson could earn. Rather, salesforce
11 remuneration was a direct function of overall OxyContin sales – the more you sell, the more you
12 make. “A lucrative bonus system encouraged sales representatives to increase sales of OxyContin
13 in their territories, resulting in large numbers of visits to physicians with high rates of opioid
14 prescriptions, as well as a multifaceted information campaign aimed at them.”³⁵

16 86. The third tactic was to increase the overall number of individual calls that the
17 salesforce placed to prescribers. “From 1996 to 2000, Purdue increased its internal sales force from
18 318 sales representatives to 671, and its total physician call list from approximately 33,400 to
19 44,500 to approximately 70,500 to 94,000 physicians.”³⁶

21 87. When combined, these tactics produced the intended result. “The use of prescriber
22 profiling data to target high-opioid prescribers – coupled with very lucrative incentives for sales
23 representatives – would seem to fuel increased prescribing by some physicians – perhaps the most
24 liberal prescribers of opioids and, in some cases, the least discriminate.”³⁷

27 ³⁴ *Id.*

28 ³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

1 88. Dr. Van Zee’s 2002 and 2009 observations regarding the direct link between
2 OxyContin marketing and overall opioid overdose mortality would, in time, be confirmed by
3 further academic work, including empirical research published by the National Bureau of Economic
4 Research in 2019.

5 89. Moreover, the legal regime under which the opioid drugs Publicis assiduously
6 marketed and sold are regulated is the *Controlled* Substances Act. Publicis sought to maximize the
7 sales of drugs known to be dangerous and addictive, and whose manufacture and distribution
8 accordingly require *control*, not the same marketing tactics otherwise used for non-addictive
9 products whose abuse liability does not routinely cause the user’s death.

10 90. In 1970, Congress enacted the Controlled Substances Act (“CSA”) in order to
11 combat the spread and use of drugs known to be dangerous and/or addictive. It is also the legal
12 regime that regulates the lawful production, possession, and distribution of substances deemed
13 deserving of control, but that have some recognized medical use.

14 91. The Drug Enforcement Administration (“DEA”) administers the act. The CSA
15 allocates substances meriting control to one of five classifications based on the characteristics of
16 each substance and the attendant risks posed.

17 92. In order to produce and market certain substances meriting control, pharmaceutical
18 companies must register with the DEA and be bound by the reporting requirements of the CSA.
19 The act requires any person who seeks to manufacture, distribute, dispense, or conduct research
20 involving any controlled substance to obtain and maintain a registration from the DEA. *See* 21
21 U.S.C. 823(e); 21 C.F.R. 1301.74(b).

22 93. The opioids that Defendants and their clients marketed are classified as Schedule II
23 controlled substances under the CSA. Schedule II substances “have a high potential for abuse for
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1 which may lead to severe psychological or physical dependence.”³⁸ As such, opioids are subject to
2 control under the CSA because the diversion of these substances poses recognized risks to public
3 health and safety.

4 94. The CSA also imposes reporting requirements on manufacturers, whereby
5 registrants must monitor and report suspicious orders of opioids. These obligations include
6 recordkeeping, whereby registrants must maintain complete and accurate inventories and records
7 of all transactions involving controlled substances and make those records available to the DEA.
8 In addition, registrants must periodically report all sales, delivery, disposal, or dispensing activities
9 of any controlled substance. Schedule II controlled substance manufacturers, such as Publicis’
10 clients, must also file Automated Reports and Consolidated Orders System (ARCOS) reports with
11 the DEA.
12

13 95. Upon information and belief, Defendants, through their efforts to increase opioid
14 sales for its clients, possessed and shared with its clients detailed information on the prescribing
15 and dispensing patterns and volumes of its clients’ Schedule II opioids. Upon information and
16 belief, McKinsey, Publicis and ZS could determine when the prescribing or dispensing of a given
17 clients’ opioid product was unusual. For instance, upon information and belief, McKinsey, Publicis
18 and ZS clients could identify aberrations in the number of units sold, doses prescribed, prescriptions
19 written per prescriber, method of payment used, and other factors relevant to changes in the volume
20 of its clients’ opioid sales.
21

22 96. The inputs necessary for a Registrant to identify suspicious orders that merit
23 reporting are the same inputs that McKinsey, Publicis and ZS collects, analyzes, and synthesizes in
24 order to define and target the marketing campaigns for its clients. Upon information and belief, the
25
26

27
28 ³⁸ See <https://www.deadiversion.usdoj.gov/schedules/#define> Schedule I substances also have a high potential for abuse and dependence. The difference is that Schedule I substances have no recognized medical use. Schedule II substances, like opioids, do.

1 same information utilized and analyzed by McKinsey, Publicis and ZS presented to their clients for
 2 purposes of devising and optimizing opioid sales and marketing efforts should have led to
 3 obligations by McKinsey's, Publicis' and ZS' clients – as registrants under the CSA - to report
 4 suspicious activity to the DEA.

5
 6 97. Many states, including Oklahoma, enacted similar state laws, rules and regulations
 7 in order to regulate the manufacture, marketing, distribution and dispensing of controlled
 8 substances and provide oversight over this unique industry.³⁹

9
 10 98. In order to keep these dangerous and addictive drugs out of the wrong hands, this
 11 closed-system of state and federal authority imposes specific duties upon Registrants to monitor,
 12 identify, halt and, perhaps most importantly, report suspicious orders of controlled substances. 21
 13 C.F.R. § 1301.74; *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

14 **c. What McKinsey Does: “Consulting is more than giving advice.”**

15 99. McKinsey is a global consulting firm with many areas of expertise, including the
 16 pharmaceutical industry. As a management consulting firm, McKinsey provides plans to managers,
 17 directors, and owners on how to run their companies or other enterprises, and helps implement
 18 those plans.

19
 20 100. Management consulting is the business of providing solutions to clients. Solutions
 21 take many forms, depending on the client's needs. “Management consulting includes a broad range
 22 of activities, and the many firms and their members often define these practices quite differently.”⁴⁰

23 101. Broadly speaking, there are two schools of management consulting. “Strategy”
 24 consulting provides big-picture advice to clients about how they approach their business: how the
 25 business is structured, which markets to compete in, potential new business lines, and mergers and
 26

27
 28 ³⁹ See 63 OK Stat. 63-2-101 *et. seq.*

⁴⁰ Arthur Turner, *Consulting is More Than Giving Advice*, Harvard Business Review, September 1982, available at:
<https://hbr.org/1982/09/consulting-is-more-than-giving-advice>

1 acquisitions. The strategy consultant provides a plan to the client that the client may choose to adopt
2 or not.

3 102. “Implementation” consulting is what comes next. If strategy consulting is providing
4 advice to a client, “implementation” work is what happens once the client has adopted the
5 consultant’s plan. After a client has adopted the strategy consultant’s recommendations, the
6 implementation consultant remains in place with the client to actually do the necessary work and
7 execute on the plan.
8

9 103. In his 1982 *Harvard Business Review* article entitled “Consulting is More Than
10 Giving Advice,” Professor Arthur Turner of the Harvard Business School described the then-
11 current state of the consulting industry’s attitude toward implementation work:
12

13 The consultant’s proper role in implementation is a matter of considerable debate in
14 the profession. Some argue that one who helps put recommendations into effect
15 takes on the role of manager and thus exceeds consulting’s legitimate bounds.
16 Others believe that those who regard implementation solely as the client’s
17 responsibility lack a professional attitude, since recommendations that are not
18 implemented (or implemented badly) are a waste of money and time. And just as
19 the client may participate in diagnosis without diminishing the value of the
20 consultant’s role, so there are many ways in which the consultant may assist in
21 implementation without usurping the manager’s job.⁴¹

18 104. Although McKinsey has historically been regarded as a “strategy” consulting firm,
19 by the time it was working with Purdue, implementation services were a core component of the
20 suite of services that McKinsey provided within the “transformational relationship” it developed
21 with its clients.⁴² Indeed, writing in 2013, Harvard Business School Professor Clayton Christensen
22 observed the decline in “pure” strategy work performed by consultants, as the industry sought to
23 diversify its income streams by offering implementation and other services to clients. “For example,
24
25
26

27 ⁴¹ *Id.*

28 ⁴² For McKinsey’s own description of its implementation services, See <https://www.mckinsey.com/business-functions/mckinsey-accelerate/how-we-help-clients/implementation> (last accessed October 19, 2020).

1 at traditional strategy-consulting firms, the share of work that is classic strategy has been steadily
 2 decreasing and is now about 20%, down from 60% of 70% some 30 years ago.”⁴³

3 105. When partnering with clients, a core component of the McKinsey relationship is
 4 discretion. “The basis of any client relationship with the firm is trust. Companies share their most
 5 competitive secrets with McKinsey with the understanding that confidentiality is paramount.
 6 McKinsey consultants aren’t even supposed to tell their own spouses about their client work.”⁴⁴
 7 McKinsey recognizes it must have its clients’ trust and make confidentiality “paramount,” as
 8 “[c]ompanies share their most competitive secrets with McKinsey” for McKinsey to do its work.⁴⁵

9 106. During the implementation phase, McKinsey essentially bonds with the client.
 10 Describing McKinsey’s approach to implementation, one McKinsey consultant stated, “In some of
 11 the most successful engagements I’ve seen, you can’t even tell the difference between a McKinsey
 12 team member and one of our clients because we working that cohesively together.”⁴⁶

13 107. Another McKinsey Senior Implementation Coach described McKinsey’s approach:
 14 “We’re in there interacting with every element of that organization, from the welders or mechanics
 15 on the front line, all the way up to the board of directors.”⁴⁷

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26 ⁴³ Clayton Christensen, Dina Wang, and Derek van Bever, “Consulting on the Cusp of Disruption,” *Harvard Business Review*, October 2013, available at <https://hbr.org/2013/10/consulting-on-the-cusp-of-disruption>

27 ⁴⁴ McDonald, *The Firm*, Pg. 308.

28 ⁴⁵ *Id.* at 308.

⁴⁶ McKinsey on Implementation, April 30, 2017, available at <https://www.youtube.com/watch?v=rEQOGVpl9CY>

⁴⁷ *Id.*

108. McKinsey's implementation team even has a logo: a rowing team.



McKinsey Careers: what's behind McKinsey Implementation's logo and success?

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109. Jenny, a Practice Manager at McKinsey, explained its significance: “The rowers symbolized to us being in the boat with the clients, doing real work and being jointly responsible for the success.”⁴⁸

110. Eugene, a partner, explained its value:

The reason McKinsey implementation works is because clients love it. The fact that we are staying longer with them, the fact that we're getting in to the trenches, the fact that we are there to walk the emotional journey with them when they're going through the tough times and really changing their companies, is what makes McKinsey implementation truly distinctive.⁴⁹

111. In the broadest of generalities, then, McKinsey's business model, as a provider of strategy and implementation consulting services, is to partner with clients to pursue business objectives identified by McKinsey. Once an objective is identified, the client and McKinsey then

⁴⁸ See “McKinsey Careers: what's behind McKinsey Implementation's logo and success?”, October 22, 2018, *available at* <https://web.archive.org/web/20200419140214/https://www.youtube.com/watch?v=3-Zx859VJtw>

⁴⁹ *Id.*

engage in concerted action as a seamless and cohesive unit in order to implement the necessary means to achieve it.

i. McKinsey’s Long-Term Partnership with the Pharmaceuticals Industry

112. Today, McKinsey’s website explains “How We Help Clients” in the pharmaceuticals industry: “Helping clients maximize commercial value by assisting with product launch, marketing, sales, and market access.”⁵⁰ McKinsey helps numerous clients throughout the pharmaceutical industry, from manufacturers to distributors and pharmacies. It often does so contemporaneously. For instance, McKinsey might advise multiple opioid manufacturers on the sales and marketing of competing branded opioid products.

113. McKinsey’s dominance of the consulting space in the pharmaceutical industry presents its own opportunity for further client service. Specifically, McKinsey also helps its clients by telling them what their competitors—who are also McKinsey clients—are doing.

114. For example, McKinsey pitched its services to Purdue on the basis that it was able to “*bring examples from other successful companies*” and perform “detailed analytics.”⁵¹

ii. The McKinsey Pharmaceuticals and Medical Products Practice Group

115. Like most management consulting companies, McKinsey organizes itself into practice groups that specialize in a given industry.

116. McKinsey has long maintained a Pharmaceuticals and Medical Products (“PMP”) industry practice group dedicated to working with pharmaceutical companies. In 2004, when McKinsey’s relationship with Purdue began, the PMP group was led by Michael Pearson. Pearson worked for McKinsey for twenty-three years and was a member of the firm’s shareholder council

⁵⁰ <https://www.mckinsey.com/industries/life-sciences/how-we-help-clients/commercial>

⁵¹ PPLPC021000601208 (emphasis added).

(McKinsey's equivalent of a board of directors) in addition to leading PMP before departing McKinsey in 2008 to helm Valeant Pharmaceuticals.⁵²

117. Pearson stated: "At McKinsey pharmaceuticals was one of our biggest industry groups."⁵³ Pearson was "not the quintessential suave and intellectual McKinsey partner. He was loud and profane and was seen, in the words of one former colleague, as 'sharp-edged and sharp elbowed.'"⁵⁴

118. Under his leadership, McKinsey's knowledge and expertise in the pharmaceutical industry was significant. By 2009, McKinsey described its capabilities: "We have an unparalleled depth of both functional and industry expertise as well as breadth of geographical reach. Our scale, scope, and knowledge allow us to address problems that no one else can. At heart, we are a network of people who are passionate about taking on immense challenges that matter to leading organizations, and often, to the world."

119. In 2012, while advising Purdue, McKinsey described PMP and its health care capabilities thusly: "Indeed, there is a doctor in the house. We have more than 1,700 consultants with significant healthcare experience, including more than 150 physicians and 250 consultants with advanced degrees in genetics, immunology, biochemical engineering, neurobiology, and other life sciences. We also have 75 consultants with advanced degrees in public health, healthcare management, and related fields."

⁵² John Gapper, *McKinsey's fingerprints are all over Valeant*, Financial Times, March 23, 2016, available at: <https://www.ft.com/content/0bb37fd2-ef63-11e5-aff5-19b4e253664a>

Notably, Rob Rosiello, a McKinsey partner who was a Director of Client Services (or "DCS") of the Purdue account alongside co-DCS'es Maria Gordian and Martin Elling, went on to join Pearson at Valeant in 2015 as Chief Financial Officer. The DCS is the partner in charge of the client account.

⁵³ Michael Peltz, *Mike Pearson's New Prescription for the Pharmaceuticals Industry*, Institutional Investor, September 3, 2014, available at: <https://www.institutionalinvestor.com/article/b14zbjfm8nf1c4/mike-pearsons-new-prescription-for-the-pharmaceuticals-industry>

⁵⁴ John Gapper, *McKinsey's fingerprints are all over Valeant*, Financial Times, March 23, 2016, available at: <https://www.ft.com/content/0bb37fd2-ef63-11e5-aff5-19b4e253664a>

120. That same year, the PMP group published a report entitled “Death of a Sales Model, or Not: Perspectives on the Evolution of Pharmaceutical Field Based Selling.”⁵⁵ In it, McKinsey partner Laura Moran co-authored a segment called “The Few, The Proud, The Super-Productive: How a ‘smart field force’ can better drive sales.” In the segment, Moran and her co-authors described various ways a pharmaceutical company could optimize its sales force. Moran worked on the Purdue account, where the strategies outlined in her article were incorporated into Project Turbocharge two years later.

121. With respect to pharmaceutical marketing, the PMP group states, “We support clients in creating high-impact strategies that maximize value, using customized tools. We also have detailed market data for all major geographic regions.”⁵⁶ PMP also works with pharma clients regarding their sales force: “Our efforts span the entire organization—we can help train and restructure sales forces, work directly in the field to provide coaching, maximize value from back-office services, develop strategies to accelerate short-term sales, and assist with company-wide commercial transformations.”⁵⁷

122. McKinsey has long considered itself a “leadership factory” for good reason.⁵⁸ Nowhere is this more apparent than the pharmaceutical industry, where, thanks to PMP’s efforts under Pearson’s leadership, McKinsey continues to reign as the dominant management consultant.

123. Consistent with PMP’s ambition that McKinsey be the dominant consultant in the pharmaceutical industry, McKinsey has blanketed the entire pharmaceutical supply chain with alumni.

⁵⁵ “Death of a Sales Model, or Not,” Pharmaceutical and Medical Product Practice, McKinsey, *available at* https://www.mckinsey.com/~media/mckinsey/dotcom/client_service/pharma%20and%20medical%20products/pmp%20new/pdfs/2012%20death%20of%20a%20sales%20model%20or%20not.pdf

⁵⁶ *See* <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/how-we-help-clients/commercial>
⁵⁷ *Id.*

⁵⁸ *See* Adam Jones, “Should business schools fear McKinsey’s leadership factory?,” *Financial Times*, May 22, 2016, *available at*: <https://www.ft.com/content/0d17f670-1612-11e6-b197-a4af20d5575e>

124. Rajiv de Silva, for instance, was appointed CEO of Endo Pharmaceutical in March 2013. Endo’s two top-selling drugs were pain medications. Endo—and de Silva, individually—have been named in multiple lawsuits related to the ongoing opioid crisis. Previously, de Silva worked with Pearson in a leadership position within PMP at McKinsey before joining Rob Rosiello, a former McKinsey partner, and Pearson at Valeant.⁵⁹ McKinsey advised Endo on its opioid business.

125. Likewise, Frank Scholz was a partner at McKinsey and a leader in the PMP group for seventeen years prior to departing in 2013 to join Mallinckrodt, another opioid manufacturer presently in bankruptcy after being named in numerous lawsuits relating to the ongoing opioid crisis. In fact, Scholz was the President of the “Specialty Generics” division of Mallinckrodt (formerly SpecGX LLC), which is the division that sold generic opioids. McKinsey advised Mallinckrodt on its opioid business.

126. Teva Pharmaceuticals,⁶⁰ another opioid manufacturer named in numerous lawsuits for its role in the opioid crisis, is led by President and Chief Executive Officer and McKinsey alumnus, Kare Schultz. He joined the company in 2017, at which point he was also appointed to Teva’s board of directors. Through an asset manager named Deerfield, McKinsey’s in-house hedge fund held a financial stake in Teva Pharmaceuticals while McKinsey advised its numerous clients on how to maximize opioid sales.⁶¹

⁵⁹ David Sell, “Endo CEO downplays Valeant link,” Philadelphia Inquirer, November 5, 2015, *available at* https://www.inquirer.com/philly/business/20151106_Endo_CEO_downplays_Valeant_link.html

⁶⁰ “Teva Pharmaceuticals” or “Teva” refers to Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc., together.

⁶¹ Gretchen Morgenson, “Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from treating addicts,” *NBC News*, February 8, 2021, *available at* <https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969>

McKinsey’s in-house hedge fund is discussed further, below.

127. McKinsey's involvement with Teva has been long-term. In 2006, upon his retirement from McKinsey, Roger Abravanel joined Teva's board of directors the following year.⁶² By 2011, Teva had acquired Cephalon, Inc., another manufacturer of opioids, as "a core part of [Teva's] strategy" of "growth through acquisitions."⁶³ Befitting the pattern, Cephalon had its own long-standing ties to McKinsey before being acquired by Teva. In 2008, when Cephalon's Executive Vice President, General Counsel, and Secretary John E. Osborn retired, he accepted a job as "an advisor on life sciences regulatory and compliance matters to the international consulting firm McKinsey & Company, Inc."⁶⁴

128. McKinsey has ties to another notable opioid industry combination: the 2012 acquisition of Actavis, Inc. by Watson Pharmaceuticals, Inc. ("Watson") for €4.25 billion. In the aftermath of the acquisition of the large European pharmaceutical company, Watson created a "Global Integration Management Office" reporting directly to its CEO, Paul Bisaro, to focus "on planning and implementing the integration of Actavis."⁶⁵ In order to achieve this critical task, Watson hired Marc Lehnen: "We were very pleased to recruit Marc from McKinsey & Company, Inc. to lead the Integration Management Office. Marc has years of experience in the generic industry and knows our culture and way of operating."⁶⁶ Notably, the press release indicates that McKinsey was already advising Watson regarding the acquisition: "*Although Marc does not formally join our Company until July, he will nevertheless be involved in the integration planning during this interim period.*"⁶⁷

⁶² Form 20-F dated December 31, 2012, Teva Pharmaceutical Industries Limited, *available at* <https://www.sec.gov/Archives/edgar/data/818686/000119312513050510/d450498d20f.htm>

⁶³ *Id.*

⁶⁴ "Cephalon General Counsel John E. Osborn to Resign Position," February 8, 2008, *available at* https://www.sec.gov/Archives/edgar/data/873364/000110465908008569/a08-5085_1ex99d1.htm

⁶⁵ "Watson Announces Formation of Global Integration Management Office to Support ending Actavis Acquisition," PR Newswire, May 9, 2012, *available at* <https://www.prnewswire.com/news-releases/watson-announces-formation-of-global-integration-management-office-to-support-pending-actavis-acquisition-150755565.html>

⁶⁶ *Id.*

⁶⁷ *Id.* (emphasis added).

1 129. Allergan,⁶⁸ another opioid manufacturer and defendant in the nationwide opioid
2 litigation, has also relied on McKinsey as a source of management candidates. McKinsey Senior
3 Adviser Christopher J. Coughlin joined Allergan’s board in 2014 and remains there today.

4 130. Abbott Labs, which partnered with Purdue in the early years of OxyContin to use
5 Abbott’s sales force to market Purdue’s drug, has been led by CEO Miles White since 1998. White
6 began his career at McKinsey around 1980.

7 131. As the preceding paragraphs make clear, McKinsey was in a truly unique position:
8 given its dominance of pharmaceutical management consulting through PMP, practically all opioid
9 industry participants were its clients. And those same clients routinely hire McKinsey consultants
10 to leadership positions within their companies. While advising multiple industry participants
11 regarding the sales of competing products, McKinsey was in a position to know confidential
12 information and trade secrets of these clients “with the understanding that confidentiality is
13 paramount.”⁶⁹

14 132. Because of its client relationships, McKinsey was, quite literally, the sole repository
15 on Earth of this collective knowledge of industry-wide tactics regarding the sales and marketing of
16 opioids, and the outcomes thereof. This unique collection of knowledge and expertise made
17 McKinsey a hub: even if any two given industry participants did not know what each other was
18 doing, McKinsey knew exactly what *both* were doing because both were clients.

19 133. McKinsey’s relationships and influence carry far beyond the manufacturers. For
20 instance, current McKinsey director Nancy Killefer has also been an independent director of
21 Cardinal Health, Inc. (“Cardinal”)—one of the “Big Three” Distributor Defendants in the ongoing
22 nationwide opioid litigation—since 2015. Chunhui Moi, Cardinal’s current Vice President of
23 Corporate Strategy, was previously an associate principal at McKinsey, where he worked for nine
24

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27
28 ⁶⁸ Allergan is part of the same corporate family as Actavis and Watson.

⁶⁹ McDonald, *The Firm*, Pg. 308.

1 years. Michele Holcomb, Cardinal's current Executive Vice President, Chief Strategy and Business
2 Development Officer, was a partner in the Global Pharmaceutical Practice at McKinsey.

3 134. McKinsey populates the "strategy" positions at the other opioid distributors as well.
4 At AmerisourceBergen, the "Director of Corporate Development and Strategy" was hired away
5 from McKinsey, where she had previously been a senior associate. AmerisourceBergen's Executive
6 Vice President and Chief Strategy Officer had previously been a partner at McKinsey.
7

8 135. At McKesson Corporation ("McKesson"), another McKinsey client, the President
9 of McKesson Specialty Health and, previously Vice President of Corporate Strategy, was Marc
10 Owen. "Prior to joining McKesson, Owen was a senior partner at McKinsey, advising
11 pharmaceutical manufacturers, healthcare providers, distributors and technology companies,
12 *including McKesson*, for more than a decade."⁷⁰ After Owen was promoted in 2012, McKesson
13 hired yet another Vice President of Corporate Strategy away from McKinsey.
14

15 136. In short, one way McKinsey adds value for a client is by knowing what all of its
16 competitors are doing. It possesses a greater body of knowledge about any given industry in which
17 it advises multiple participants than any individual participant does itself.

18 **iii. The Transformational Relationship**

19 137. McKinsey has long touted the notion of a "transformational relationship." It is the
20 goal of every client relationship McKinsey develops and, McKinsey argues, the best way to extract
21 value from a client's use of McKinsey's services. McKinsey is not a one-off seller of advice for
22 any given CEO's problem of the day. Rather, McKinsey argues that real value for the client derives
23 from an ongoing "transformational" relationship with the firm.⁷¹
24

25
26 ⁷⁰ "Marc Owen Appointed President of McKesson Specialty Health," McKesson, January 31, 2012, *available at*
27 [https://www.mckesson.com/about-mckesson/newsroom/press-releases/2012/marc-owen-appointed-president-of-](https://www.mckesson.com/about-mckesson/newsroom/press-releases/2012/marc-owen-appointed-president-of-mckesson-specialty-health/)
28 [mckesson-specialty-health/](https://www.mckesson.com/about-mckesson/newsroom/press-releases/2012/marc-owen-appointed-president-of-mckesson-specialty-health/) (emphasis added)

⁷¹ Duff McDonald, *The Firm*, Pg. 136-37 ("McKinsey no longer pitched itself as a project-to-project firm; from this point forth [the late 1970s], it sold itself to clients as an ongoing prodder of change, the kind a smart CEO would keep around indefinitely.").

138. At its core, the “transformational relationship” is *long-term*. It is the antithesis of a one-off contract wherein McKinsey performs one discreet project for a client and then concludes its business. Rather, “once McKinsey is inside a client, its consultants are adept at artfully creating a feedback loop through their work that purports to ease executive anxiety but actually creates more of it.”⁷² The long-term result can be “dependence” on the McKinsey consultants. “We insinuate ourselves,” Ron Daniel, McKinsey’s then-managing partner, told *Forbes* in 1987.⁷³

139. “They have follow-on work not just because they’re good at what they do, but because they are trained in how to manage these kinds of client relationships. They understand that the core reality is the relationship and the conversation, and that any particular engagement is merely epiphenomenal,” explained Alan Kantrow, formerly the editor of *McKinsey Quarterly*.⁷⁴

140. This strategy of weaving itself into all aspects of its clients’ business proved enormously successful for McKinsey over the years. It was a strategy McKinsey encouraged its consultants to take with clients to great effect:

The sell worked: Once ensconced in the boardrooms of the biggest corporate players in the world, McKinsey rarely left, ensuring a steady and growing flow of billings for years if not decades. In 2002, for example, *BusinessWeek* noted that at that moment, the firm had served four hundred clients for fifteen years or more.⁷⁵

141. Another aspect of the transformational relationship McKinsey develops with clients is the development and marketing of “leave-behind” products, such as software applications, that are sold to clients as tools that can be used by the business on an on-going and recurring basis, separate and apart from McKinsey’s project-based consulting work. As described by Harvard

⁷² *Id.* at pg. 6. Purdue provides a fine example of this feedback loop in action. In 2008, when McKinsey was advising Purdue regarding Risk Evaluation and Mitigation Strategies (“REMS”) for OxyContin required by the FDA, McKinsey partner Maria Gordian wrote to fellow partners Martin Elling and Rob Rosiello regarding progress in the “REMS work” as well as “Broader Strategy work.” Regarding the latter, Gordian noted that Purdue board members Jonathan Sackler and Peter Boer “basically ‘blessed’ [Craig Landau] to do whatever he thinks is necessary to ‘save the business.’ . . . *I believe there is a good opportunity to get another project here.*” MCK-MAAG-0117875 (emphasis added). Indeed, after the REMS work was completed, McKinsey continued to work on “Broader Strategy work” for another decade.

⁷³ John Merwin, “We Don’t Learn from Our Clients, We Learn from Each Other,” *Forbes*, October 19, 1987.

⁷⁴ Duff McDonald, *The Firm*, Pg. 185.

⁷⁵ *Id.* at pg. 136.

1 Business School Professor Clayton Christensen, starting in 2007, “McKinsey & Company initiated
 2 a series of business model innovations that could reshape the way the global consulting firm
 3 engages with clients. One of the most intriguing of these is McKinsey Solutions, software and
 4 technology-based analytics and tools that can be embedded at a client, providing ongoing
 5 engagement outside the traditional project-based model.”⁷⁶

7 142. McKinsey’s relationship with Purdue provides an example of the deployment of
 8 these “leave-behind” products. One McKinsey Solution is a pharmaceutical sales and marketing
 9 workforce optimization tool called FieldGuide, a proprietary software application McKinsey sells
 10 to clients. “The FieldGuide tool optimizes salesforce deployment and territory design through
 11 advanced geospatial analysis that leverages both market-potential insights across device categories
 12 and advanced sales-response curve analysis.”⁷⁷ McKinsey sold it to Purdue for the purpose of
 13 optimizing Purdue’s OxyContin salesforce.
 14

15 **d. McKinsey and Purdue: A Case Study in Transformation**

16 143. Indeed, McKinsey’s work with Purdue is a prime example of the transformational
 17 relationship in action. McKinsey counted Purdue as a client at least as early as 2004, three years
 18 *before* Purdue’s parent and officers first pleaded guilty to misbranding OxyContin in 2007.
 19 McKinsey was actively working with Purdue to increase OxyContin sales despite that guilty plea
 20 and continued to do so throughout the time period that Purdue and its advisors were bound by the
 21 terms of the Corporate Integrity Agreement entered in to alongside the guilty plea. McKinsey’s
 22 work with Purdue continued through at least 2018.
 23

24 144. McKinsey staffed at least forty known consultants to Purdue, from senior partners
 25 all the way down through engagement managers and entry-level associates. Throughout the
 26

27 ⁷⁶ Clayton Christensen, Dina Wang, and Derek van Bever, “Consulting on the Cusp of Disruption,” *Harvard Business Review*, October 2013, available at <https://hbr.org/2013/10/consulting-on-the-cusp-of-disruption>

28 ⁷⁷<https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/how-we-help-clients/medtech/marketing-and-sales>

1 unfolding of the nationwide opioid crisis that only continued to worsen after the 2007 guilty plea,
 2 McKinsey remained steadfast alongside the Sacklers and Purdue every step of the way. The *mea*
 3 *culpas* would come only later.

4 145. McKinsey partner Maria Gordian, in her March 26, 2009 “EY 2009 Impact
 5 Summary” internal report to McKinsey director Olivier Hamoir and McKinsey’s Personnel
 6 Committee, recounted her accomplishments that year on the Purdue account. The document is an
 7 annual self-assessment produced by McKinsey partners. In it, Gordian described the state of firm’s
 8 relationship for Purdue:
 9

10 With client work extending through the 3rd quarter, and several additional proposals
 11 in progress, we continue to expand the depth and breadth of our relationships at
 12 Purdue. We look forward to deepening our relationships with the Sackler family and
 13 serving them on key business development issues, and to expanding our relationship
 14 with [John] Stewart and other members of the senior management team.⁷⁸

14 146. Gordian even described herself as a counselor to Richard Sackler in the same
 15 memorandum, in addition to being a “point of contact for the Board and Sackler family.”⁷⁹

16 147. The continued expansion of the depth and breadth of McKinsey’s relationship with
 17 Purdue was an ever-present internal goal for McKinsey, as it was accompanied by recurring and
 18 ever-increasing client billings.

19 148. By 2014, both the breadth and depth of McKinsey’s relationship with Purdue had
 20 expanded dramatically. During the 2009 to 2014 period in particular, Purdue relied extensively on
 21 McKinsey to develop and implement its sales and marketing strategy for OxyContin. But
 22 McKinsey’s work for Purdue involved many other facets of Purdue’s business beyond sales and
 23 marketing, including general and administrative consulting, review of product acquisition,
 24
 25

26 _____
 27 ⁷⁸ The Ad Hoc Group of Non-Consenting States’ Statement in Support of the Official Committee of Unsecured
 28 Creditors’ Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012,
In re Purdue Pharma, Inc., filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex 7, Pg. 48; MCK-MAAG
 0118669.

⁷⁹ *Id.*

1 evaluation of research and development, advising Purdue on the design of clinical studies, risk
2 management, and interactions with regulators.

3 149. McKinsey's sales and marketing work for Purdue focused on creating and
4 implementing strategies and tactics to bolster the sales of OxyContin, a Schedule II drug that is
5 widely recognized as among the most frequently diverted and abused opioids. As Purdue faced
6 growing scrutiny, McKinsey also helped the company protect its public image and profit from the
7 market for illicit opioids, which McKinsey's industry-wide efforts helped to promote and maintain.

8 150. McKinsey understood the Sacklers' goals for Purdue and the work it would need to
9 perform to maintain and grow Purdue's opioid profits amidst a growing epidemic of addiction and
10 abuse. Part of McKinsey's work involved assessing the "underlying drivers" of OxyContin's
11 (financial) performance. As described below, these drivers boil down to two things: (1) a
12 widespread deceptive marketing campaign and (2) fueling an illicit market for non-medical use.
13 Purdue entered into guilty pleas arising out of both types of conduct in 2007 and 2020, respectively.
14 McKinsey delved into the "granular" aspects of Purdue's sales and promotion. And, throughout the
15 two companies' long-term relationship, McKinsey understood Purdue's business "both in terms of
16 content and culture," as its own renewed consulting agreement assured in 2013.

17
18
19 **i. 2004: McKinsey and Purdue Meet**

20 151. On March 1, 2004, McKinsey entered into a Master Consulting Agreement with
21 Purdue for services that would be defined from time to time.⁸⁰ The Agreement was signed on
22 McKinsey's behalf by Rob Rosiello, then a senior partner in the PMP practice group. After a ruling
23 that held patents on OxyContin unenforceable due to Purdue misleading the patent office,
24 McKinsey stepped in to help Purdue.⁸¹

25
26
27
28 ⁸⁰ PPLPC012000069192

⁸¹ *Id.*

152. The Master Consulting Agreement [REDACTED]

153. From 2004 through 2008, McKinsey advised Purdue on research and development, business development, and product licensing related to Purdue's opioid products.⁸⁴ Consistent with its business model, McKinsey leveraged these projects into growth of its "Broader Strategy work" also underway with Purdue.⁸⁵ Specifically, in October 2008, Purdue retained McKinsey for broad strategy work after two board members "blessed" Purdue executive Craig Landau with doing "whatever he thinks is necessary to 'save the business'" after the 2007 criminal plea and introduction of generic competition to the older OxyContin.⁸⁶

ii. 2007: Purdue Pleads Guilty to Misbranding OxyContin and is Bound by a Corporate Integrity Agreement

154. On May 10, 2007, John Brownlee, United States Attorney for the Western District of Virginia, announced the guilty plea of the Purdue Frederick Company, the parent of Purdue Pharma, relating to the misbranding of OxyContin. Brownlee stated,

Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal. In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted

⁸² *Id.*

⁸³ PPLPC020000034087

⁸⁴ PPLPC013000116218; PPLP004401340

⁸⁵ MCK-MAAG-0117875

⁸⁶ *Id.*

1 to OxyContin; a drug that Purdue led many to believe was safer, less subject to
2 abuse, and less addictive than other pain medications on the market.

3 155. Purdue Frederick Company as well as three of Purdue's officers, pleaded guilty to
4 the misbranding of OxyContin pursuant to various provisions of the Federal Food, Drug, and
5 Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*

6 156. Purdue admitted that "supervisors and employees, with the intent to defraud or
7 mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion,
8 and less likely to cause tolerance and withdrawal than other pain medications." Part of this
9 deceptive messaging included highlighting OxyContin as a long-acting ("LA") or extended release
10 ("ER") opioid and suggesting it created less chance for addiction than "immediate release" opioids
11 because it had fewer "peak and trough" blood level effects or "did not cause a 'buzz' or euphoria"
12 in the same manner as these other opioids.
13

14 157. Concurrent with its guilty plea, Purdue entered into a Corporate Integrity Agreement
15 with the Office of Inspector General of the United States Department of Health and Human Services
16 on May 7, 2007. Purdue's compliance obligations under the Corporate Integrity Agreement ran for
17 a period of five years, and ultimately terminated in January 2013.⁸⁷
18

19 158. Pursuant to the Corporate Integrity Agreement, Purdue was obligated to implement
20 written policies regarding its compliance program and compliance with federal health care program
21 and Food and Drug Administration requirements, including:

22 a. "selling, marketing, promoting, advertising, and disseminating Materials or information
23 about Purdue's products in compliance with all applicable FDA requirements, including
24 requirements relating to the dissemination of information that is fair and accurate . . .
25 including, but not limited to information concerning the withdrawal, drug tolerance, drug
addiction or drug abuse of Purdue's products";

26 b. "compensation (including salaries and bonuses) for Relevant Covered Persons engaged
27 in promoting and selling Purdue's products that are designed to ensure that financial
28

⁸⁷ See <https://www.justice.gov/opa/press-release/file/1329576/download>

1 incentives do not inappropriately motivate such individuals to engage in the improper
2 promotion or sales of Purdue's products"; and

3 c. "the process by which and standards according to which Purdue sales representatives
4 provide Materials or respond to requests from [health care providers] for information about
5 Purdue's products, including information concerning withdrawal, drug tolerance, drug
6 addiction, or drug abuse of Purdue's products," including "the form and content of Materials
7 disseminated by sales representatives," and "the internal review process for the Materials
8 and information disseminated by sales representatives."

9 159. Purdue was obligated to engage an Independent Review Organization to ensure its
10 compliance with the strictures of the Corporate Integrity Agreement and to file compliance reports
11 on an annual basis with the Inspector General.

12 160. In the wake of its accession to the Corporate Integrity Agreement, Purdue faced
13 newly imposed constraints on its sales and marketing practices. The Corporate Integrity Agreement
14 was a problem to solve. Despite the agreement's constraints (i.e., do not lie about OxyContin),
15 Purdue and its controlling owners, the Sackler family, still intended to maximize OxyContin sales.

16 **iii. The Sacklers React to the "Concentration of Risk" Posed to Them by** 17 **Purdue's Opioid Business.**

18 161. The Sackler family has owned and controlled Purdue and its predecessors since
19 1952. At all times relevant to this Complaint, individual Sackler family members occupied either
20 six or seven of the seats on Purdue's board of directors, and at all times held a majority of Board
21 seats. To advise the board of directors of Purdue Pharma was to advise the Sackler family. The
22 interests of the Sackler family and the Purdue board of directors, and Purdue itself, as a privately
23 held company, were all aligned. Practically, they were indistinguishable.⁸⁸

24 162. As a result of the 2007 guilty plea, the Sacklers made the strategic decision to
25 distance the family from Purdue, which was regarded, in the words of Richard Sackler, as an
26 increasingly dangerous "concentration of risk" for Purdue's owners. Ten days after the guilty plea

27 ⁸⁸ Craig Landau, soon to become CEO of Purdue, acknowledged in May 2017 that Purdue operated with "the Board of
28 Directors serving as the 'de facto' CEO." The future CEO of the company, in other words, understood that he would
have little practical power despite his new title. The owners ran the business.

was announced, David Sackler wrote to his father, Richard Sackler, and uncle, Jonathan Sackler, describing precisely what that “risk” was: legal liability for selling OxyContin. In response to Jonathan stating that “there is no basis to sue ‘the family,’” David replied:

Message

From: David Sackler [REDACTED]
Sent: 5/17/2007 11:08:08 PM
To: 'Sackler, Jonathan'; Sackler, Dr Richard [REDACTED]
CC: Ives, Stephen A. [REDACTED]
Subject: RE: Idea
Attachments: image001.jpg

Well I hope you're right, and under logical circumstances I'd agree with you, but we're living in America. This is the land of the free and the home of the blameless. We will be sued. Read the op-ed stuff in these local papers and ask yourself how long it will take these lawyers to figure out that we might settle with them if they can freeze our assets and threaten us.

163. Given concern over this “concentration of risk,” the two sides of the Sackler family spent considerable time and energy debating the best way to achieve distance from Purdue, and collectively considered a variety of options for doing so. One option was to sell the company to or merge the company with another pharmaceutical manufacturer. They discussed Shire as a possible target, as were Cephalon, UCB, and Sepracor, Inc. The proceeds of such a transaction could then be re-invested in diversified assets, thereby achieving the Sacklers’ desired distance from opioids.

164. Mortimer D.A. Sackler advocated for a sale or merger in a February 21, 2008, email to Richard Sackler (a former president and co-chairman of Purdue) and several others, writing, “The pharmaceutical industry has become far too volatile and risky for a family to hold 95% of its wealth in. It simply is not prudent for us to stay in the business given the future risks we are sure to face and the impact they will have on the shareholder value of the business and hence the family’s wealth.” The risk he referred to was, at least in significant part, further liability related to OxyContin.

165. Another option was to have Purdue borrow money in order to assure Purdue had adequate funds to continue operating while the Sacklers, as owners, began to make substantial distributions of money from the company to themselves. Once again, the proceeds of the

1 distributions could then be re-invested in diversified assets, thereby achieving the Sacklers' desired
2 distance.

3 166. In order to pursue either of these options, the Sacklers needed to maximize opioid
4 sales in the short term so as to make Purdue—by then the subject of substantial public scrutiny—
5 appear either as an attractive acquisition target or merger partner to another pharmaceutical
6 manufacturer or as a creditworthy borrower to a lender.

7
8 167. In short, the Sacklers planned to engage in a final flurry of opioid pushing in order
9 to rid themselves of their pharmaceutical company dependency for good.

10 168. In fact, in the years after the 2007 guilty plea, Purdue would retain only the absolute
11 minimum amount of money within it as possible: \$300 million. Purdue was required to retain that
12 amount pursuant to a partnership agreement with separate company. Otherwise, all the money was
13 distributed to its owners.⁸⁹

14
15 169. Given the complexity of the problem, the Sacklers and Purdue realized that they
16 would need assistance in achieving these internally contradictory objectives. Purdue did not have
17 the capabilities in-house to design and implement a sales strategy for OxyContin that would achieve
18 the Sacklers' objectives. They turned to the global management consulting firm McKinsey, which
19 had already been advising the Sacklers and Purdue for at least three years, for help with their new
20 problem.

21
22 170. Notably, under the terms of Paragraph II.C.1(b) of the Corporate Integrity
23 Agreement, McKinsey, as a contractor to Purdue performing sales and marketing functions for the
24 company, was itself a "Covered Person" subject to the strictures of the Agreement.⁹⁰

25
26 ⁸⁹ See Jared S. Hopkins, *At Purdue Pharma, Business Slumps as Opioid Lawsuits Mount*, Wall Street Journal, June 30,
27 2019, available at: https://www.wsj.com/articles/purdue-pharma-grapples-with-internal-challenges-as-opioid-lawsuits-mount-11561887120?mod=hp_lead_pos6

28 ⁹⁰ The relevant language in the Corporate Integrity Agreement provides: "'Covered Persons' includes . . . all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions . . . on behalf of Purdue." PDD1712900096.

iv. **Purdue Tasks McKinsey with Boosting Opioid Sales in Light of the Guilty Plea and Corporate Integrity Agreement.**

171. The Sacklers faced a problem: the need to grow OxyContin sales as dramatically as possible so as to make Purdue an attractive acquisition target or borrower, while at the same time appearing to comply with the Corporate Integrity Agreement. As one Purdue executive stated of Purdue's attitude toward the Corporate Integrity Agreement: "They did not listen to their critics and insisted they had just a few isolated problems. After the settlement, they didn't change—the way the sales force was managed and incentivized, everything stayed the same."⁹¹

172. Purdue and the Sacklers were well aware of the constraints posed by the Agreement. Indeed, during a May 20, 2009 Executive Committee Meeting, the discussion led to whether Purdue should have a single sales force marketing all Purdue products, including OxyContin, or instead to "create a separate Sales Force for Intermezzo (a sleeping pill) that would be comprised of approximately 300 representatives." John Stewart, Purdue's then-CEO, saw an opportunity, and asked if the Corporate Integrity Agreement would apply if Purdue were to launch Intermezzo and another Purdue product, Ryzolt (a branded version of Tramadol, another narcotic painkiller), using the separate sales force. Might the new drug launch fall outside of the Corporate Integrity Agreement, he asked?⁹²

173. It would not, he was told by Bert Weinstein, Purdue's Vice President of Compliance.⁹³

174. Given the tension between compliance with the Corporate Integrity Agreement and the desire to sell more OxyContin, Purdue needed help.

⁹¹ David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times, September 9, 2018, available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

⁹² PPLPC012000226606, Purdue Pharma Executive Committee Meeting Notes and Actions, May 20, 2009, Pg. 2.

⁹³ *Id.*

1 175. Ethan Rasiel, a former McKinsey consultant, has described the typical way
2 McKinsey begins working with a client: “An organization has a problem that they cannot solve
3 with their internal resources. That’s the most classic way that McKinsey is brought in.”⁹⁴

4 176. Such was the case with Purdue. Because it did not have the requisite expertise to
5 address the problems posed by the Corporate Integrity Agreement internally, Purdue expanded on
6 its already-existing relationship with McKinsey to devise a sales and marketing strategy to increase
7 opioid sales despite the Corporate Integrity Agreement and growing concern about the
8 “concentration of risk” that Purdue’s business of selling opioids posed to its owners.

9 177. McKinsey’s task was to thread the needle: to increase OxyContin sales despite the
10 strictures imposed by the five-year Corporate Integrity Agreement. This McKinsey did,
11 turbocharging⁹⁵ the sales of a drug it knew fully well was addictive and deadly, while purporting
12 to respect to the Corporate Integrity Agreement.

13 178. In short, Purdue would pay money to McKinsey in exchange for McKinsey enabling
14 the company how to sell as much OxyContin as conceivably possible so that the Sacklers could
15 obtain cash to diversify their investment holdings away from Purdue and keep their money safe
16 from the reach of court judgments, fines, and penalties they feared.

17 179. Consistent with their plan to dissociate themselves from the company, the Sacklers
18 appointed Mr. Stewart as the CEO of Purdue in 2007. The Sacklers viewed Stewart as someone
19 loyal to the family. He had previously worked for a division of Purdue in Canada. Stewart’s job
20 was to assist the Sacklers with the divestiture or eventual orderly wind-down of Purdue. Stewart
21 was paid more than \$25 million for his services to Purdue from 2007 through 2013.

22 ⁹⁴ *How McKinsey Became One of the Most Powerful Companies in the World*, CNBC, June 6, 2019 available at:
23 https://www.youtube.com/watch?v=BBmmMj_maII

24 ⁹⁵ If the description is overbearing, note that it is McKinsey’s own, as described below.

1 180. Purdue’s Executive Committee discussed Stewart’s concerns regarding the
2 constraints posed by the Corporate Integrity Agreement on May 20, 2009. Within weeks, McKinsey
3 was working with Purdue to devise and implement new marketing strategies for OxyContin.

4 181. Stewart, as CEO, was in charge of the relationship with McKinsey. He controlled
5 workflow to and from McKinsey and required his personal approval for any work orders with
6 McKinsey.
7

8 182. In addition, Purdue’s Vice President of Corporate Compliance, “responsible for
9 developing and implementing policies, procedures, and practices designed to ensure compliance
10 with the requirements set forth in the [Corporate Integrity Agreement],” reported directly to
11 Stewart.⁹⁶

12 183. Throughout their relationship, McKinsey routinely obtained information from,
13 advised, communicated with, and ultimately worked for the Purdue board of directors, controlled
14 by the Sackler family.
15

16 184. McKinsey would also work in granular detail with the Purdue sales and marketing
17 staff, led during the relevant period by Russell Gasdia, Vice President of Sales and Marketing.

18 185. From as early as June 2009 and continuing at least through July 14, 2014, Purdue
19 routinely relied upon McKinsey to orchestrate its sales and marketing strategy for OxyContin. The
20 relationship was characterized by ongoing interactions between teams from McKinsey and Purdue
21 regarding not only the *creation* of an OxyContin sales strategy, but also its *implementation*.
22 McKinsey was a real presence at Purdue. “A team of McKinsey analysts went in-house, camping
23 out in a conference room at Purdue headquarters.”⁹⁷
24
25
26

⁹⁶ PDD1712900096.

⁹⁷ Patrick Radden Keefe, *Empire of Pain* 302 (2021). In September, McKinsey named Mr. Keefe’s history of the Sackler family and Purdue and the opioid crisis to its 2021 shortlist for “Business Book of the Year.” See <https://www.mckinsey.com/about-us/new-at-mckinsey-blog/for-your-reading-list-the-2021-business-book-of-the-year-shortlist>

1 **v. Purdue Relies on McKinsey.**

2 186. Purdue hired McKinsey not only to give advice, but to devise and then implement a
3 deceptive marketing strategy. For example, for one “major initiative” with Purdue, “McKinsey
4 forecast[ed] a potential incremental increase in sales in the \$200-400mm range” over a three-year
5 period, “[w]hen properly implemented.”⁹⁸

6
7 187. McKinsey is not cheap, either. Indeed, hiring McKinsey is an expensive proposition.
8 A single junior consultant—typically a recent college or business school graduate—runs clients
9 millions of dollars annually.⁹⁹ McKinsey is a highly selective employer and advertises that its
10 employees join “for the opportunity to apply their talents to complex, important challenges.”¹⁰⁰
11 “Talent” is key to McKinsey’s model; clients pay for the best and brightest.

12
13 188. A client does not choose to pay McKinsey unless it expects to receive benefits it
14 could not have obtained within its own organization. McKinsey offers solutions to clients facing
15 challenges they feel they cannot adequately address on their own. This model has been a stunning
16 success for McKinsey. In 2008, McKinsey’s annual revenue was \$6 billion. Today, the firm earn
17 more than \$10 billion in revenue each year.¹⁰¹

18
19 189. Clients pay these exorbitant rates for a reason: McKinsey’s plans and partnership
20 work. Even critics of the consulting industry recognize the unique efficacy of McKinsey’s work.
21 JPMorgan Chase CEO Jamie Dimon once derided consultants as “substituted management” and
22 stated that “consultants can become a disease for corporations.” Dimon made one exception to this

23
24
25
26 ⁹⁸ PPLPC012000257444

27 ⁹⁹ Ian MacDougal, *How McKinsey is Making \$100 Million (and Counting) Advising on the Government’s Bumbling Coronavirus Response*, ProPublica (July 15, 2020), <https://www.propublica.org/article/how-mckinsey-is-making-100-million-and-counting-advising-on-the-governments-bumbling-coronavirus-response>.

28 ¹⁰⁰ <https://www.mckinsey.com/about-us/overview>

¹⁰¹ Forbes, *McKinsey & Company* (retrieved September 9, 2021), <https://www.forbes.com/companies/mckinsey-company/?sh=1201a12624c1>.

rule: McKinsey.¹⁰² Given unique levels of trust, respect, and access by major corporations across the United States and the world, McKinsey has unmatched power to affect how those corporations behave.

190. When Purdue entered into a “Master Consulting Agreement” with McKinsey in 2004, Purdue explicitly recognized McKinsey “has a fine reputation as well as excellent experience and relationships in our industry,” which Purdue was counting on to boost its opioids business.¹⁰³

191. Purdue explicitly recognized that McKinsey stepped in to help Purdue “protect [its] sales and continue to *grow our business*.”¹⁰⁴

192. Furthermore, that the Sacklers, as board members of Purdue, relied on McKinsey in their conduct of Purdue affairs is an admitted fact. In a public filing in the recent Purdue bankruptcy proceedings, the one side of the Sackler family conceded that they did so: “McKinsey is widely recognized as ‘a leading management consulting firm’ and the Former Directors were statutorily entitled to rely on such expertise.”¹⁰⁵

vi. McKinsey Delivers.

193. Purdue, as a monoline manufacturer of opioids, relied on McKinsey in practically all aspects of its business.

1. Courting the Regulators: “We All Feel Responsible.”

194. One critical aspect of Purdue’s operations, given its status as a producer of controlled substances, was regulatory compliance. McKinsey guided Purdue through practically all of its interactions with regulators whose efforts to protect the public might pose threats to Purdue’s business.

¹⁰² Duff McDonald. *Behind the singular mystique of McKinsey & Co.* The Guest Blog. CNBC. Sept 25, 2013. Available at: <https://www.cnbc.com/2013/09/25/behind-the-singular-mystique-of-mckinsey-co.html>

¹⁰³ PPLPC012000069192

¹⁰⁴ *Id.* (emphasis added).

¹⁰⁵ *In re: Purdue Pharma, L.P.*, No. 19-23649, Doc. 3441-1, at ¶ 328 (Aug. 5, 2021).

195. McKinsey advised Purdue on how to approach the FDA in light of its criminal conviction and retain business in light of the reputational damage to the company and to OxyContin after the admissions in its guilty plea.

196. In 2008, Purdue submitted a New Drug Application for a reformulation of OxyContin, ostensibly to make it more difficult to abuse by extracting the active ingredient from it or otherwise defeating the time-release mechanism in OxyContin tablets—i.e., another product Purdue would later deceptively promote as safer than and less prone to abuse than it was.

197. Having advised Purdue on the design of tests of reformulated OxyContin as part of Purdue's FDA submission, McKinsey knew that reformulated OxyContin could still be abused. Purdue nonetheless touted its introduction of reformulated OxyContin and another ADF opioid as evidence of its good corporate citizenship and commitment to protecting the public. McKinsey worked with the Sacklers to prepare for Purdue's meetings with the FDA.

198. On January 20, 2009, McKinsey partner Maria Gordian wrote to partners Rob Rosiello and Martin Elling to update them on these ongoing efforts with Purdue:

We had a very good FDA rehearsal yesterday *with several family members present*. The team did an outstanding job on the study. [P]reparing the client and executing the mock meeting. We are off to DC today for the actually (sic) FDA meeting tomorrow.¹⁰⁶

199. Gordian's email to Rosiello and Elling forwarded encouraging words from Richard Sackler. He wrote to his daughter, Marianna:

I am writing to tell you how impressed I was by the preparation for the FDA meeting. Both the method and the process as well as the content was excellent and a major departure from efforts like this in the past. Please share with the team my views and best wishes for a successful interchange with the FDA.¹⁰⁷

Marianna forwarded the well-wishes to Gordian and the team at McKinsey.

¹⁰⁶ The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex D, Pg. 25 (emphasis added).

¹⁰⁷ *Id.*

1 200. In September 2009, Purdue made a presentation to the FDA advisory committee
2 considering its application for its reformulated OxyContin and stated that the new formulation
3 would deter abuse. According to metadata, the PowerPoint presentation was prepared by
4 McKinsey.

5 201. The FDA approved the reformulation of OxyContin in April 2010.¹⁰⁸

6 202. Having successfully navigated the approval process with McKinsey's chaperoning,
7 Purdue then proceeded to market the ADF version of OxyContin as a solution to opioid abuse and
8 as a reason that doctors could continue to safely prescribe their opioids.
9

10 203. In 2020, two FDA advisory committees evaluating the impact of the reformulated
11 OxyContin concluded that reformulated OxyContin did not, in fact, substantially reduce abuse.
12

13 204. At the same time as it worked to rehabilitate Purdue's image with the FDA,
14 McKinsey, in parallel, advised Purdue on how to limit FDA regulations aimed at mitigating the
15 risks of opioid use. In 2008, shortly after Purdue's criminal plea, the FDA requested Purdue submit
16 a proposed "Risk Evaluation and Mitigation Strategy" ("REMS") for OxyContin. McKinsey
17 provided Purdue with drafts of the submission.¹⁰⁹ Indeed, McKinsey was crucial in devising
18 Purdue's response to the FDA's request for a REMS proposal from Purdue. Gordian informed
19 Rosiello and Elling on October 23, 2008, that John Stewart, Purdue's CEO, "is aware of the critical
20 role we are playing in pulling REMs together and is very appreciative." In the same email, she
21 noted that "the family" was focused "on the response to the non-approval letter" from the FDA.¹¹⁰
22

23 205. In 2009, the FDA expanded its scope to a class-wide extended release/long-acting
24 REMS program.
25

26 _____
¹⁰⁸ See <https://www.fda.gov/media/126835/download>

27 ¹⁰⁹ PDD8901578031

28 ¹¹⁰ The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex C, Pg. 22.

1 206. Seeking to avoid a requirement that prescribers undergo mandatory training on
 2 OxyContin’s risks or management or obtain certification before prescribing OxyContin, which
 3 would limit the numbers of available prescribers, Purdue turned to McKinsey. McKinsey found the
 4 cost to Purdue of a system to verify completion of prescriber education before prescriptions could
 5 be filled would be \$50 million—an estimate Purdue used to oppose efforts for more rigorous risk
 6 management strategies.¹¹¹ [REDACTED]
 7 [REDACTED]
 8 [REDACTED]
 9 [REDACTED]
 10 [REDACTED]¹¹²

11 207. Armed with McKinsey’s analysis, Purdue’s strategy on REMS was effective. The
 12 REMS program avoided verification and enrollment provisions that would harm Purdue’s profits.

13 208. Meanwhile, based on McKinsey’s work on extended-release opioid REMS,
 14 McKinsey was aware of warnings and adverse events included within the OxyContin medication
 15 guide and communications plans, including risks of overdose and adverse events including
 16 dizziness and lethargy.
 17

18 209. In June 2009, McKinsey helped Purdue prepare for an FDA advisory committee
 19 meeting. [REDACTED]
 20 [REDACTED]
 21 [REDACTED]

22 210. McKinsey prepared for Purdue an “FDA Advisory Committee on Reformulated
 23 OxyContin: Question & Answer Book” in September 2009, with questions including “Why should
 24 we trust you?” In response, McKinsey recommended Purdue say “We acknowledge mistakes made
 25 in the past[;]” “We have x, y and z measures in place that did not exist before[;]” and “[a]t all levels,
 26

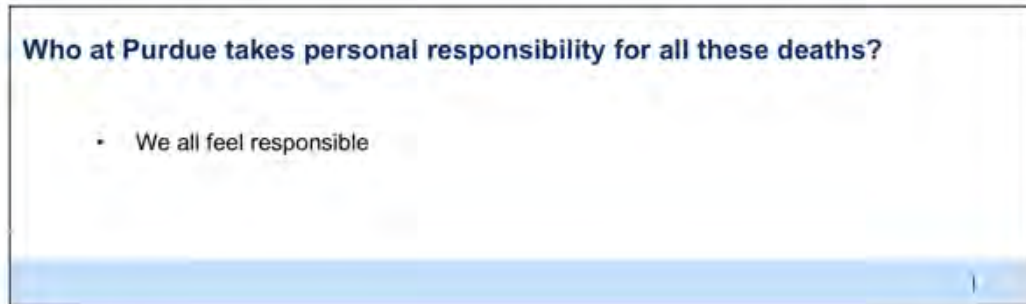
27 _____
 111 PDD8901530124

28 112 PPLPC019000622253

113 PDD8901645845

Purdue's focus is on maintaining the highest ethical standards and meeting the needs of patients[.]”¹¹⁴

211. Sometimes, McKinsey's work was as obfuscating as it was self-revealing. To the question of “Who at Purdue takes personal responsibility for all these deaths?[,]” McKinsey offered the following response:¹¹⁵



2. The Granularity of Growth

212. To this end, McKinsey prides itself on certain managerial techniques it professes to have detailed knowledge of and expertise in deploying. These techniques are generally applicable to problems encountered by many businesses; they are conceptual frameworks that McKinsey deploys when tasked with solving a problem for a client.

213. After Purdue's first guilty plea, the Sacklers desired dramatic, short-term growth of Purdue's opioid sales so as to increase the company's attractiveness as an acquisition target or borrower while allowing the Sacklers to take money out of the company. One service McKinsey offers to its clients is to tell them how to grow.

214. In order to identify growth opportunities for a client, McKinsey espouses a “granular” approach to identifying which subsets of the client's existing business are the sources

¹¹⁴ MCK-MAAG-0152135

¹¹⁵ The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents for *In Camera* Review, Doc. No. 2012, *In re Purdue Pharma, Inc.*, filed November 18, 2020, Case No. 19-23649 (S.D.N.Y.), Ex F, Pg. 39.

1 of growth, and exploiting them for all they are worth. In August 2008, McKinsey directors Patrick
 2 Viguerie and Sven Smit, together with Mehrdad Baghai, published a treatise on the matter: *The*
 3 *Granularity of Growth: How to Identify the Sources of Growth and Drive Enduring Company*
 4 *Performance* (Wiley, April 2008). “The key is to focus on granularity, to breakdown big-picture
 5 strategy into its smallest relevant components.”¹¹⁶
 6

7 215. Previously, in an article in *McKinsey Quarterly* (coincidentally published the same
 8 month that Purdue pled guilty), the authors explained:

9 Our research on revenue growth of large companies suggests that executives should
 10 “de-average” their view of markets and develop a granular perspective on trends,
 11 future growth rates, and market structures. Insights into subindustries, segments,
 12 categories, and micromarkets are the building blocks of portfolio choice. Companies
 will find this approach to growth indispensable in making the right decisions about
 where to compete.¹¹⁷

13 216. Additionally, McKinsey encouraged a granular assessment of the geography of
 14 corporate growth. “The story gets more precise as we disaggregate the company’s performance on
 15 the three growth drivers in 12 product categories for five geographic regions.”¹¹⁸
 16

17 217. One can imagine this strategy applied to a seller of, say, cartons of milk. If
 18 McKinsey were to perform an analysis of the milk seller’s sales and marketing and discover that
 19 the profit margin on milk cartons sold to university cafeterias in dairy-producing states is much
 20 greater than the margin on cartons sold at convenience stores in the southwest, and further that the
 21 milk seller has previously devoted equal amounts of time and resources selling to both university
 22 cafeterias and convenience stores, then McKinsey would likely advise the client to deploy
 23 additional resources towards selling milk to university cafeterias in dairy-producing states.
 24
 25
 26

27 ¹¹⁶ *The granularity of growth*, Book Excerpt, McKinsey & Company, March 1, 2008, available at:
<https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-granularity-of-growth>

28 ¹¹⁷ Mehrdad Baghai *et. al.*, *The granularity of growth*, McKinsey Quarterly, May 2007, available at:
<https://www.mckinsey.com/featured-insights/employment-and-growth/the-granularity-of-growth>

¹¹⁸ *Id.*

McKinsey's "granular" approach to the milk seller's business channels has identified a way to increase higher margin sales, leading to newfound growth and profitability for the client.

218. Rather than milk, McKinsey deployed this strategy on OxyContin, a controlled substance, after its manufacturer pled guilty to misrepresenting the addictive and deadly properties of the drug.

3. "Identifying Granular Growth Opportunities for OxyContin"

219. McKinsey's granular analysis of Purdue's OxyContin sales efforts led to the implementation of a number of strategies to sell more pills.

220. By January 2010, McKinsey informed Purdue, in accordance with the lessons of McKinsey's granular growth analysis, that Purdue could generate "\$200-400mm" in additional annual sales of OxyContin by implementing McKinsey's strategies.¹¹⁹

221. In November 2010, a McKinsey report instructed sales reps to maximize profits by "emphasizing [the] broad range of doses"—which meant pushing the doses that were highest and most profitable.¹²⁰

222. In 2012, John Stewart assigned McKinsey to "understand the significance of each of the major factors affecting OxyContin's sales."¹²¹

223. This McKinsey did in excruciatingly granular detail, analyzing each sales channel for Purdue's opioids to identify weaknesses, opportunities, and to suggest courses of action to improve performance. Many core themes of McKinsey's work would be crystallized in a series of presentations and updates made to the Sackler family and to Purdue's board of directors in the summer of 2013 entitled "Identifying Granular Growth Opportunities for OxyContin."

a. Marketing – Countering Emotional Messages

¹¹⁹ PPLPC012000257443; PPLPC012000257446

¹²⁰ PPLPC018000346294

¹²¹ PPLPC020000587064

1 224. From the outset of McKinsey’s known work for Purdue, the work was grim. In June
2 2009, McKinsey teamed with Purdue’s then-Chief Medical Officer (and current CEO) Craig
3 Landau and his staff to discuss how best to “counter emotional messages from mothers with
4 teenagers that overdosed in [sic] OxyContin.”

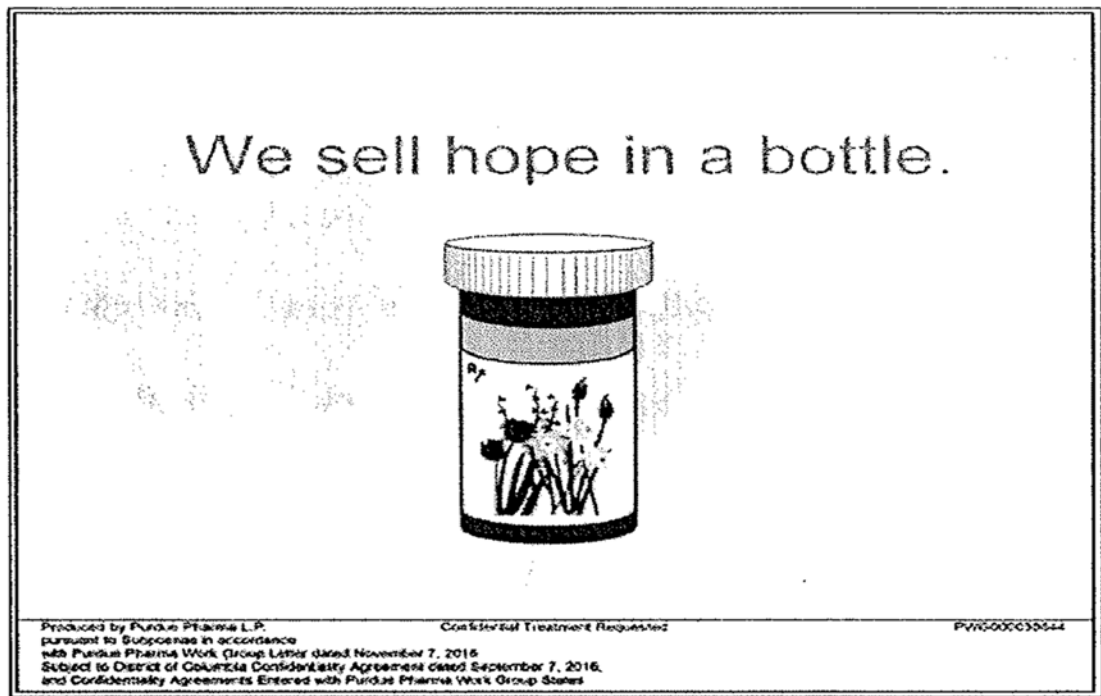
5 225. Months later, McKinsey advised Purdue to market OxyContin based on the false
6 and misleading notion that the drug can provide “freedom” and “peace of mind” for its users, give
7 patients “the best possible chance to live a full and active life,” and concomitantly reduce stress
8 and isolation.¹²²

9 226. These marketing claims were tailored to avoid any pitfalls that the Corporate
10 Integrity Agreement might hold. While false and misleading, these claims regarding “freedom” and
11 “peace of mind” of OxyContin users were narrowly tailored in order to avoid representations
12 regarding “the withdrawal, drug tolerance, drug addiction or drug abuse of Purdue’s products,” as
13 specified in Section III.B.2.c of the Corporate Integrity Agreement.¹²³
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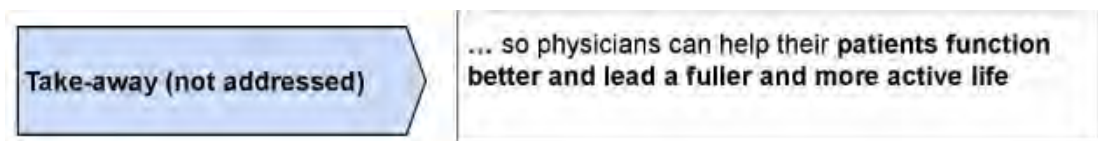
28 ¹²² PPLPC023000239858

¹²³ PDD1712900096

227. Purdue's marketing materials from that time period are illustrative of the approach.¹²⁴



228. Likewise, McKinsey informed Purdue that by highlighting the ability to “tailor the dose” and treat a “broad range of appropriate patients,” the prescriber-takeaway would be that “physicians can help their patients function better and lead a fuller and more active life,” even though this conclusion was not to be explicitly addressed.¹²⁵



229. Claims that OxyContin improved function and quality of life were not supported by substantial evidence and, in addition, failed to take into account risks of addiction. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.¹²⁶ A Centers for Disease

¹²⁴ *Tennessee v. Purdue Pharma L.P.*, Case No. 1-173-18 (Compl. May 15, 2018) ¶ 24.

¹²⁵ PPLPC019000329253

¹²⁶ The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See*

Control and Prevention guideline, following a “systematic review of the best available evidence,” concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.”¹²⁷ According to the CDC director, “for the vast majority of patients, the known, serious, and too-often- fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”¹²⁸

230. In addition to crafting carefully-tailored quality of life assurances designed to avoid the pitfalls of the Corporate Integrity Agreement, McKinsey invented other misleading marketing efforts for Purdue.

231. For instance, McKinsey urged Purdue to capitalize on OxyContin’s extended-release characteristics in another way: marketing OxyContin’s twelve-hour dosing as though users only need to take OxyContin twice a day, thus requiring fewer pills. OxyContin in fact was well known to wear off after eight to ten hours in many patients, however. What McKinsey called “convenient,” would later be called “a [d]escription of Hell.”

232. This misleading assurance of twelve-hour relief is especially pernicious, as end-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the

Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010) (rejecting claims that Actavis’ opioid, Kadian, had an “overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”). ALLERGAN_MDL_00387583; Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008) (finding the claim that “patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”). ALLERGAN_CA_00161496. The FDA’s warning letters were available to McKinsey on the FDA website.

¹²⁷ CDC Guideline at 2, 18.

¹²⁸ Thomas R. Frieden and Debra Houry, New England Journal of Medicine, “Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline” at 1503 (Apr. 21, 2016).

1 Washington University School of Medicine in St. Louis, called OxyContin’s twelve-hour dosing
 2 “the perfect recipe for addiction.”¹²⁹ Many patients will exacerbate this cycle by taking their next
 3 dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount
 4 of opioids they are taking. Promotion of twelve-hour dosing, without disclosing its limitations, is
 5 misleading because it implies that the pain relief supplied by each dose lasts twelve hours.

6
 7 233. In addition to designing misleading marketing messages, McKinsey even suggested
 8 encouraging a new channel through which those messages could be delivered to prescribers.
 9 McKinsey encouraged the tactic of “patient pushback,” wherein McKinsey and Purdue would
 10 foment patients to directly lobby their doctors for OxyContin even when those physicians expressed
 11 reservations regarding the administration of Purdue’s opioids.

12
 13 234. The idea was that McKinsey and Purdue could spread their own message through
 14 pain patients who would be perceived as more credible sources suggesting a need for controlled or
 15 extended-release opioid—even though the team devising this strategy would have known that
 16 extended-release opioids did not substantially control pain or thwart addiction better than lower-
 17 dose, immediate release opioids.¹³⁰

18
 19 235. McKinsey also coached Purdue on building “trust” (which from its vantage point,
 20 McKinsey knew was misplaced) in Purdue following its criminal conviction.

21 **b. Targeting – Selling More OxyContin to Existing**
 22 **High Prescribers**

23 236. Perhaps the key insight McKinsey provided was, using its granular approach, to
 24 identify historically large prescribers and target ever more sales and marketing resources on them,
 25 without any regard for, and indeed conscious disregard of, patient safety. Physician targeting
 26 proved effective. McKinsey advised Purdue that visiting high-prescribing doctors many times per

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 28 ¹²⁹ Harriet Ryan, “‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem,” Los Angeles Times, May 5,
 2016, available at <http://www.latimes.com/projects/oxycontin-part1/>.

¹³⁰ PDD8901645845

1 year increased sales. This relentless drive to increase sales and create greater availability of opioids
2 was made with no notable concern about the parallel increase in opioid-related deaths, abuse, and
3 misuse.

4 237. On January 20, 2010, Purdue's board was informed of the ongoing work McKinsey
5 was performing concerning a new "physician segmentation" initiative whereby McKinsey would
6 analyze the opioid prescribing patterns of individual physicians to identify those that had
7 historically been the highest prescribers.¹³¹ McKinsey then worked with Purdue's sales and
8 marketing staff to specifically target those prescribers with a marketing blitz to encourage even
9 further prescribing.
10

11 238. Purdue trained its sales force in tactics to market to these high prescribers based on
12 McKinsey's insights and designed in conjunction with McKinsey.
13

14 239. Many of the historically highest prescribers of OxyContin—those same individuals
15 that McKinsey urged Purdue to target for ever more prescriptions—had prescribed Purdue's
16 OxyContin *before* the 2007 guilty plea and had already been subjected to Purdue's
17 misrepresentations regarding OxyContin that were the subject of that guilty plea.
18

19 240. McKinsey identified these physicians—those that had already been influenced by
20 Purdue's misrepresentations and were thus already high prescribers—as optimal targets for a
21 massive marketing push to sell more OxyContin.

22 241. McKinsey worked assiduously with Purdue over many years to continually refine
23 this approach and required ever-more granular data for its analysis. More than three years after the
24 initial introduction of the physician segmentation initiative, McKinsey requested, and Purdue
25 provided, "prescriber-level milligram dosing data" so that McKinsey could further analyze the
26 individual amounts of OxyContin prescribed by individual physicians.
27
28

¹³¹ PPLPC012000257446

1 242. At the same time, it requested this “prescriber-level milligram dosing data” from
2 Purdue, McKinsey urged the Sacklers to strictly manage the target lists of each sales representative
3 to assure that the maximum amount of each sales representative’s time was spent with the most
4 attractive customers.

5 243. On July 23, 2013, Purdue’s board discussed concerns about “the decline in higher
6 strengths” of Purdue’s opioids as well as an observed decline in “tablets per Rx.” In order to assure
7 that the threat to OxyContin sales growth be addressed, McKinsey was assigned “to actively
8 monitor the number and size of opioid prescriptions written by individual doctors.”¹³²

9 244. In unveiling Project Turbocharge to Purdue and the Sacklers, McKinsey stated that
10 the most prolific OxyContin prescribers wrote “25 times as many OxyContin scripts” as less prolific
11 prescribers and urged Purdue and the Sacklers to “make a clear go-no go decision to ‘Turbocharge
12 the Sales Engine’” by devoting substantial capital toward McKinsey’s plan.¹³³

13 245. McKinsey also stated that increased numbers of visits by sales representatives to
14 these prolific prescribers would increase the number of opioid prescriptions that they would write.
15 This singular focus on increasing prescriptions was not coupled with colorable concern for the
16 patient population.

17 246. By November 2013, McKinsey had obtained the physician-level data they had
18 previously requested and continued to study ways to sell additional OxyContin prescriptions by
19 refining and targeting the sales pitch to them. The Purdue board was kept apprised of McKinsey’s
20 progress.

21 247. Not only did McKinsey identify which doctors prescribed the most of Purdue’s
22 opioids, McKinsey also recommended segmenting prescribers into “types” and tailoring messages
23 and tactics to the different prescriber profiles. For prescribers dubbed “Early Adopting Experts”
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28 ¹³² PPLP004307354

¹³³ PPLP004409890

1 and “Proactive Teachers,” defined by a willingness to use extended release opioids, including in
 2 opioid naïve patients (patients who were not already using opioids), McKinsey urged emphasizing
 3 that its seven tablet strengths provide flexibility to “tailor the dose” to customer needs.¹³⁴ Upon
 4 information and belief, this message aimed to encourage prescribers to initiate and maintain patients
 5 on OxyContin long-term by reminding them they could increase the dose as patients became
 6 tolerant with long-term use (rather than discontinue use when the drug lost its effectiveness).

8 248. In its October 26, 2009, presentation, “OxyContin – driving growth through stronger
 9 brand loyalty,”¹³⁵ McKinsey proposed tactics to turnaround declining sales, “[e]nhance loyalty to
 10 OxyContin among loyalist prescribers,” “[c]onvert[ing] ‘fence sitters’ into more loyal OxyContin
 11 prescribers,” and “[p]rotect OxyContin’s market share[.]”¹³⁶ In other words, McKinsey proposed
 12 increasing sales by pushing both willing and reluctant physicians to prescribe more OxyContin.

14 249. McKinsey also recommended a strategy to target those prescribers who did not
 15 regularly prescribe OxyContin—so-called “Resigned Followers and ER Delayers” —encouraging
 16 them to “increase step-up” to extended-release opioids. These were physicians with “low comfort
 17 with extended-release opioids.” McKinsey encouraged Purdue to emphasize to them the “range of
 18 appropriate patients.” In other words, McKinsey’s strategy recommended that Purdue encourage
 19 prescribers to use OxyContin earlier in a patient’s treatment for a wider range of patients and for
 20 longer periods of time.

22 c. Titration – Selling Higher Doses of OxyContin

23 250. McKinsey understood that the higher the dosage strength for any individual
 24 OxyContin prescription, the greater the profitability for Purdue. Of course, higher dosage strength,

27 ¹³⁴ MCK-MDL2296-0126522

28 ¹³⁵ *Id.*

¹³⁶ *Id.* at 2.

1 particularly for longer periods of use, also contributes to opioid dependency, addiction and abuse.
2 Nonetheless, McKinsey advised Purdue to focus on selling higher strength dosages of OxyContin.

3 251. Consistent with its granular growth analysis, as early as October 26, 2009,
4 McKinsey advised the Sacklers and the Purdue board that Purdue should train its sales
5 representatives to “emphasiz[e] the broad range of doses,” which would have the intended effect of
6 increasing the sales of the highest (and most profitable) doses of OxyContin.¹³⁷
7

8 252. McKinsey’s work on increasing individual prescription dose strength continued
9 throughout the time period McKinsey worked with Purdue. The Sacklers were informed on July
10 23, 2013, that Purdue had identified weakness in prescribing rates among the higher doses of
11 OxyContin and reassured the Sacklers that “McKinsey would analyze the data down to the level of
12 individual physicians” in order to study ways to maximize the sales of the highest-dose OxyContin
13 pills.
14

15 253. Purdue implemented McKinsey’s suggestions through adopting the marketing
16 slogan to “Individualize the Dose” and by 2013 encouraged its sales representatives to “practice
17 verbalizing the titration message” when selling Purdue’s opioids to prescribers.¹³⁸

18 254. McKinsey would have known, however, that higher doses of opioids carry greater
19 risk. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent
20 dose (“MED”) per day) as part of long-term opioid therapy are three to nine times more likely to
21 suffer overdose from opioid-related causes than those on low doses. As compared to available
22 alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive
23 effects of opioids develops at a slower rate than tolerance to opioids’ analgesic effects. The Centers
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28 ¹³⁷ PPLPC018000346294

¹³⁸ PPLP003450924

1 for Disease Control and Prevention also recognize that higher doses of opioids tend to increase
2 overdose risks relative to any potential patient benefit.¹³⁹

3 255. Claims that opioids could be taken in ever-increasing strengths to obtain pain relief,
4 without disclosing that higher doses increased the risk of addiction and overdose, are deceptive and
5 misleading. They were particularly important to promotional efforts, however, because patients on
6 opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve
7 pain relief. Marketers needed to generate a comfort level among doctors to ensure the doctors
8 maintained patients on the drugs even at the high doses that became necessary.

10 256. Purdue adopted McKinsey's [REDACTED] proposal.¹⁴⁰ [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 257. The titration messaging worked. Nationwide, based on an analysis by the *Los*
16 *Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses
17 greater than sixty milligrams per day, which converts to the ninety MED that the CDC guideline
18 urges prescribers to “avoid” or “carefully justify.”¹⁴²

19 **d. Covered Persons – Sales Quotas and Incentive**
20 **Compensation**
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25 ¹³⁹ Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States,
26 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>

26 ¹⁴⁰ PPLPC023000251226 [REDACTED] see also
27 PPLPC012000243668 [REDACTED] PPLPC012000245087 [REDACTED]
28 [REDACTED] PPLPC012000246009 [REDACTED] PPLPC021000265092 [REDACTED]

¹⁴¹ PKY183123435

¹⁴² CDC Guideline at 16.

1 258. McKinsey urged the use of quotas and bonus payments to motivate Purdue's sales
2 force to sell as many OxyContin prescriptions as possible. As McKinsey described it, "[r]evision
3 to incentive comp could better align reps to Purdue's economics."¹⁴³

4 259. Notably, this behavior was prohibited by the 2007 Corporate Integrity Agreement,
5 which required Purdue to implement written policies regarding "compensation (including salaries
6 and bonuses) for [sales representatives] engaged in promoting and selling Purdue's products that
7 are designed to ensure that financial incentives *do not inappropriately motivate such individuals to*
8 *engage in the improper promotion or sales of Purdue's products.*"¹⁴⁴

9 260. By 2010, Purdue had implemented a four-year plan, consistent with McKinsey's
10 strategy, to dramatically increase the quota of required annual sales visits by Purdue sales
11 representatives to prescribers. The quota was 545,000 visits in 2010, 712,000 visits in 2011,
12 752,000 in 2012, and 744,000 visits in 2013.

13 261. On August 15, 2013, as part of their "Identifying Granular Growth Opportunities
14 for OxyContin" presentation, McKinsey urged the Sacklers to "establish a revenue growth goal
15 (*e.g.*, \$150M incremental stretch goal by July 2014) and set monthly progress reviews with CEO
16 and Board."¹⁴⁵

17 262. In its "Identifying Granular Growth Opportunities for OxyContin" presentation to
18 the Purdue board in July 2013, McKinsey nonetheless urged Purdue, in addition to increasing the
19 focus of the sales force on the top prescribers, to increase the overall quotas for sales visits for
20 individual sales representatives from 1,400 to 1,700 annually.

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¹⁴³ PPLPC012000441016

¹⁴⁴ PDD1712900096 (emphasis added).

¹⁴⁵ PPLP004409890

263. In 2013, McKinsey identified one way that Purdue could squeeze more productivity out of its sales force: by slashing *one third* of the time that Purdue devoted to training its sales force (from 17.5 days per year to 11.5 days):

One possible way to attain benchmark ~1500 calls per year is to decrease training days by ~6 days and increase calls per day by 5% One possible route to benchmark

Current call activity		Potential new allocation	
Number of "on territory" days per year		Number of "on territory" days per year	
Item	Days ¹	Item	Days ¹
Number of working days	260	Number of working days	260
Holidays	-11.3	Holidays	-11.3
Vacation and other time off	-27.2	Vacation and other time off	-27.2
Trainings and meetings	-17.5	Trainings and meetings	-11.5
Other company-related time off of field	-4.3	Other company-related time off of field	-4.3
Total days	199.7	Total days	205.7
Avg calls per day	x 7	Avg calls per day	x 7.35
Total calls per year	1398	Total calls per year	1512

¹ Purdue 2012 Actual data was used for this analysis

SOURCE: Purdue; team analysis

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264. By eliminating one third of the amount of time sales representatives were required to be in training, McKinsey projected that Purdue could squeeze an additional 5% of physical calls per day out of its newly less-trained sales force.

265. Additionally, McKinsey developed and advised Purdue on a new incentive compensation structure for the sales representatives, who were Covered Persons pursuant to the Corporate Integrity Agreement. McKinsey knew that, combined with the strictures of sales quotas and less training for the sales force, bonus/incentive compensation to the sales representatives based on the number of OxyContin prescriptions the representative produced could be a powerful driver of incremental OxyContin sales, without regard for patient safety.

vii. Transformation: Purdue and McKinsey Adopt and Implement McKinsey's Strategies.

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2 266. As early as September 11, 2009, McKinsey determined and told Purdue that it could
3 generate \$200 million to \$400 million in additional annual sales of OxyContin by implementing
4 McKinsey's strategy based on the opportunities its granular growth analysis had identified.
5 McKinsey reiterated its assurances regarding the hundreds of millions of dollars of additional
6 OxyContin sales on January 20, 2010.

7 267. Purdue accepted and, with McKinsey's ongoing assistance, implemented
8 McKinsey's strategies for selling and marketing OxyContin.

9
10 268. For instance, in January 2010, Purdue was training its sales and marketing force on
11 the new sales tactics based on a "physician segmentation" initiative that McKinsey urged. The
12 strategy developed as a result of McKinsey's granular analysis of OxyContin sales channels. The
13 initiative sought to identify the most prolific OxyContin prescribers and then devote significant
14 resources towards convincing those high prescribers to continue to prescribe ever more OxyContin,
15 in higher doses, for longer times, to ever more patients.

16
17 269. On January 20, 2010, the Purdue board was informed of the progress in
18 implementing McKinsey's "physician segmentation" initiative.

19 270. This transformative collaboration would continue over the course of the relationship
20 between Purdue and McKinsey.

21 271. During the time that McKinsey was working with Purdue, Purdue deliberately
22 minimized the importance of the Corporate Integrity Agreement. In 2008, Carol Panara joined the
23 Purdue sales force from rival Novartis. She would stay with the company until 2013, during which
24 time McKinsey was responsible for increasing OxyContin sales at Purdue, and culminating with
25 the implementation of McKinsey's "Project Turbocharge," beginning September 2013.

26
27 272. Ms. Panara stated that the 2007 guilty plea was deliberately minimized by the
28 company in presentations to its sales staff: "They said, 'We were sued, they accused us of mis-

1 marketing, but that wasn't really the case. In order to settle it and get it behind us we paid a fine.'
 2 You had the impression they were portraying it as a bit of a witch hunt."¹⁴⁶ (Purdue and its
 3 executives paid \$634.5 million in fines.)

4 273. Consistent with McKinsey's mandate, McKinsey devised methods for sales staff to
 5 sell OxyContin to doctors while at the same time maintaining technical compliance with the
 6 Corporate Integrity Agreement. Ms. Panara stated that, though she was told she could not flatly
 7 claim that OxyContin was better or safer than other opioids, "she was trained to talk about product
 8 in ways that implied that it was safer." She might tout OxyContin's twelve-hour formulation to a
 9 prescriber. "You could say that with a shorter-acting medication that wears off after six hours, there
 10 was a greater chance the patient was going to jump their dosing schedule and take an extra one a
 11 little earlier. We couldn't say [it was safer], but I remember we were told that doctors are smart
 12 people, they're not stupid, they'll understand, they can read between the lines."¹⁴⁷

13 **viii. Project Turbocharge a/k/a Evolve to Excellence a/k/a E2E**

14 274. The Corporate Integrity Agreement expired in January 2013. With this restriction
 15 lifted, McKinsey devised additional marketing and sales strategies for Purdue to further increase
 16 OxyContin sales.

17 275. On May 14, 2013, McKinsey entered into a "Statement of Services to the Master
 18 Consulting Agreement" (the "2013 Agreement") with Purdue to "conduct a rapid assessment of the
 19 underlying drivers of current OxyContin performance, identify key opportunities to increase near-
 20 term OxyContin revenue and develop plans to capture priority opportunities." [REDACTED]
 21 [REDACTED]
 22 [REDACTED]
 23 [REDACTED]
 24 [REDACTED]
 25 [REDACTED]
 26 [REDACTED]

27 ¹⁴⁶ David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times, September 9, 2018,
 28 available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

¹⁴⁷ *Id.*

¹⁴⁸ PPLPC030000770531

1 276. The 2013 Agreement stated, “We have a long history of partnership with Purdue,
2 and we would make best efforts to leverage our understanding of your business – both in terms of
3 content and culture.” It was signed by then-principal Arnab Ghatak, who would “lead the team with
4 senior leadership from Rob Rosiello and Martin Elling.” Elling was a leader of McKinsey’s PMP
5 group.¹⁴⁹

6
7 277. McKinsey was tasked with “Identifying Granular Growth Opportunities for
8 OxyContin,” conducting an “assessment of the underlying drivers of current OxyContin
9 performance,” identifying “key opportunities to drive near-term OxyContin performance,” and
10 developing “plans to capture priority opportunities.”¹⁵⁰

11 278. For purposes of the project, McKinsey would need “[f]ull access to work done to
12 date and key data.”¹⁵¹ And, [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 279. Staff told the Sacklers that McKinsey would study how to get doctors to prescribe
16 more OxyContin,¹⁵³ how to use incentive compensation to push reps to generate more prescriptions,
17 how to use “patient pushback” to get doctors to prescribe more opioids, and how to keep patients
18 on opioids longer.¹⁵⁴

19 280. The 2013 Agreement would lead to Project Turbocharge, McKinsey’s successful
20 bid to transform Purdue’s sales and marketing efforts for OxyContin now that Purdue was no longer
21 bound by the Corporate Integrity Agreement.
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26 ¹⁴⁹ *Id.*

27 ¹⁵⁰ PPLPC030000770531 / MCK-MAAG-0024283

28 ¹⁵¹ *Id.*

¹⁵² PPLPC012000431809

¹⁵³ PPLPC012000431262

¹⁵⁴ *Id.*; PPLPC012000431266

1 281. In the summer of 2013, McKinsey made multiple recommendations to Purdue's
2 board to increase OxyContin revenue, and urged the Sackler family to "make a clear go-no-go
3 decision to 'Turbocharge the Sales Engine.'"

4 282. Purdue, like McKinsey, recognized that the initiative was no small thing. An internal
5 Purdue email states that [REDACTED]
6 [REDACTED]
7 [REDACTED]

8 283. The Sacklers were impressed. On August 15, 2013, Richard Sackler emailed
9 Mortimer D.A. Sackler, "[T]he discoveries of McKinsey are astonishing."

10 284. Eight days later, on August 23, 2013, McKinsey partners met with the Sackler
11 family—not the Purdue board of directors—to pitch Project Turbocharge. Dr. Arnab Ghatak, one
12 of the McKinsey partners leading the Purdue account, recounted the meeting to fellow McKinsey
13 partner Martin Elling in an email exchange: "[T]he room was filled only with family, including the
14 elder statesman Dr. Raymond [Sackler] We went through exhibit by exhibit for about 2 hrs . .
15 . . They were extremely supportive of the findings and our recommendations . . . and wanted to
16 strongly endorse getting going on our recommendations."¹⁵⁶
17

18 285. Elling, a co-leader of the Purdue account, remarked in the same email
19 correspondence that McKinsey's "findings were crystal clear to" the Sacklers, and that the Sacklers
20 "gave a ringing endorsement of 'moving forward fast.'"¹⁵⁷
21

22 286. As a result of the Sackler family endorsement of McKinsey's proposals, the
23 following month Purdue implemented Project Turbocharge based on McKinsey's
24 recommendations. In adopting "Project Turbocharge," Purdue acknowledged the improper
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28 ¹⁵⁵ PPLPC012000437344

¹⁵⁶ MCK-MDL2996-0403095

¹⁵⁷ *Id.*

1 connotations of the name, and re-christened the initiative the decidedly more anodyne “E2E: Evolve
2 to Excellence.”¹⁵⁸

3 287. Evolve to Excellence (“E2E”) was the theme of Purdue’s 2014 National Sales
4 Meeting.

5 288. CEO John Stewart also told sales staff that board member Paolo Costa was a
6 “champion for our moving forward with a comprehensive ‘turbocharge’ process,” referring to
7 McKinsey’s plan.

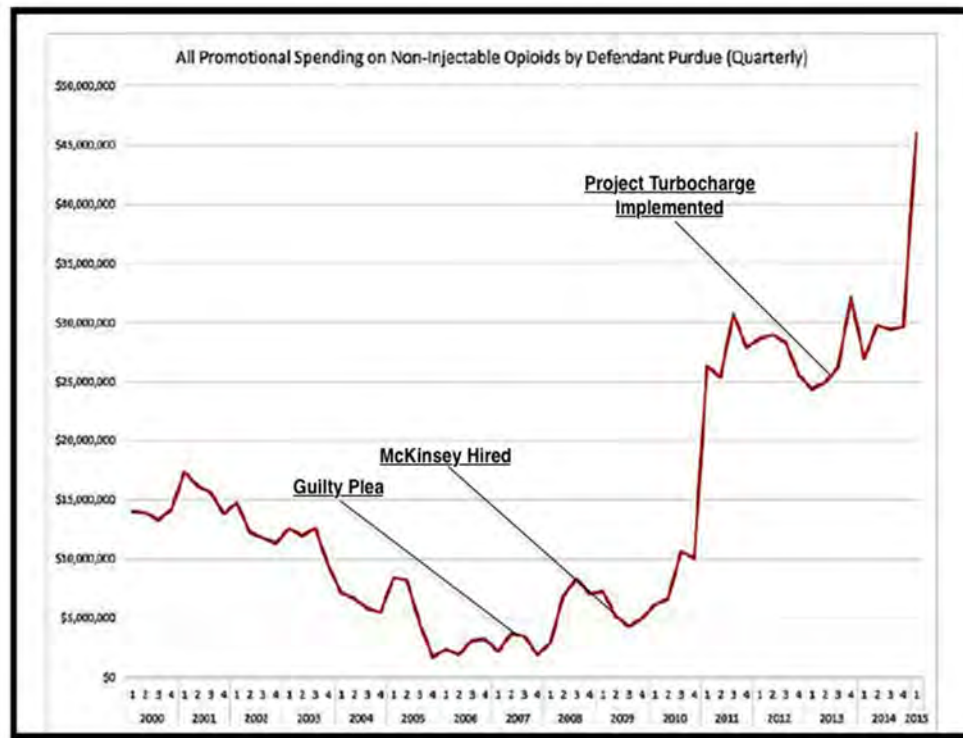
8 289. After Purdue adopted McKinsey’s recommendations, McKinsey continued to work
9 with Purdue sales and marketing staff reporting to Russell Gasdia during Purdue’s implementation
10 of McKinsey’s recommendations.

11 290. In fact, the entire E2E initiative was overseen by McKinsey and some Purdue
12 executives, who together comprised the E2E Executive Oversight Team and Project Management
13 Office.

14 291. At the same time, the Sacklers were kept informed of the implementation of
15 McKinsey’s OxyContin strategy. According to a September 13, 2013, board agenda, the board
16 discussed with the Sacklers the ongoing implementation of McKinsey’s sales tactics.

17 292. Evolve to Excellence called for a *doubling* of Purdue’s sales budget. Under
18 McKinsey’s prior tutelage, Purdue’s promotional spending had already skyrocketed. McKinsey’s
19 ongoing influence on Purdue’s operations after the 2007 guilty plea is stark:
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27 ¹⁵⁸ Regarding the name change, CEO John Stewart wrote to McKinsey partners Rob Rosiello and Arnab Ghatak on
28 August 15, 2013: “Paolo Costa was especially engaged in the discussion and he (among others) will be a champion for
our moving forward with a comprehensive ‘turbocharge’ process – *though we do need to find a better and more
permanently appropriate name.*” PPLPC012000436626 (emphasis added).



293. At the time of McKinsey's first known work for Purdue, Purdue spent approximately \$5 million per quarter on sales and marketing. By the time McKinsey's Project Turbocharge was implemented, total quarterly sales and marketing spending at Purdue exceeded \$45 million, an increase of 800%.

294. Project Turbocharge continued despite the arrival of a new CEO at Purdue. On January 17, 2014, new CEO Mark Timney received reports from McKinsey emphasizing that, in order to increase profits, Purdue must again increase the number of sales visits to "high-value" prescribers, i.e., those that prescribe the most OxyContin.¹⁵⁹

¹⁵⁹ In fact, recent deposition testimony suggests McKinsey may have been responsible for the fact that Timney was given the CEO job at Purdue in the first place. On October 30, 2020, Timney provided the following testimony (emphasis added):

Q: Are you familiar with McKinsey & Company?

A: I decline to answer on the ground that I may not be compelled to be a witness against myself in any proceeding.

Q: Did individuals at McKinsey assist you in getting hired as the CEO of Purdue?

A: I decline to answer on the ground that I may not be compelled to be a witness against myself in any proceeding.

1 295. Purdue and McKinsey worked together to implement “Turbocharging the Sales
2 Engine.” [REDACTED]

3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 296. McKinsey and Purdue also worked together on an “implementation plan” for E2E,
7 with McKinsey taking on the role of “executive oversight” of projects including the creation of
8 target lists, internal dashboards to track progress, and changes to Purdue’s incentive compensation
9 plan consistent with E2E.¹⁶¹

10 **1. Targeting High Subscribers**

11 297. Project Turbocharge called for revising the existing process for targeting high-
12 prescribing physicians, with a shift from targeting solely on the basis of prescription deciles to
13 considering additional factors. Based on its analysis, McKinsey told Purdue that “[t]here is
14 significant opportunity to slow the decline of OxyContin by calling on more high-value physicians”
15 and that “[t]he revenue upside from sales re-targeting and adherence could be up to \$250 million.”

16 298. The core objective of McKinsey’s initiative was to ensure that Purdue was “making
17 calls on the highest potential customers with the right frequency to maximize prescribing potential.”
18

19 299. McKinsey determined and advised Purdue that the top half of prescribing physicians
20 “write on average 25 times more scripts per prescriber” than the lower half. McKinsey advised that
21 Purdue would see a greater return on its sales investment by focusing on these targets, including on
22

23
24
25 In fact, McKinsey appears to have played a substantial role in the succession of several Purdue CEO’s. Martin
26 Elling, in his 2018 annual self-assessment, provided the following example of “how I deliver impact:”
27 “Actively managing CEO/CXO transitions: ... from Michael Friedman to John Stewart (2007) to Mark
28 Timney (2014) to Craig Landau (2017) at Purdue.” MCK-MDL2996-0357931. “I drove our introduction of
Purdue in 2004 and then, with Rob Rosiello, built it into a substantial and sustaining client... We have served
across four CEOs and are now helping the new leadership team adapt to a world of headwinds for their core
product OxyContin,” he added. MCK-MDL2996-0357931.

¹⁶⁰ PPLPC021000615265

¹⁶¹ MCK-MDL2996-0180338, at 0180340

prescribers with alarming prescribing patterns that raised red flags they were writing “prescriptions” for non-medical use. McKinsey’s plan aimed at boosting sales of OxyContin by targeting the highest volume opioid prescribers, without addressing whether the expanded sales would be for an illicit market.

300. McKinsey found that Purdue did not “focus on the highest potential docs,” measured both by the number of prescriptions and reimbursement considerations.¹⁶² One McKinsey analyst urged McKinsey to recommend Purdue target “[l]iterally, at least all” prescribers in the top 20% of prescribers, “minus another few percent who are no sees[.]”¹⁶³ McKinsey team lead Arnab Ghatak replied that “they probably have 20% no see[], but i’d also assume there are not many high writers that are no see.”¹⁶⁴ (“No see” prescribers are prescribers who do not accept visits from pharmaceutical sales representatives. Thus, McKinsey recognized that most of the highest volume prescribers, or “high writers” of prescriptions, were willing to entertain sales visits from sales representatives.)

301. “To put this in perspective,” McKinsey stated,

the average prescriber in decile 5-10 [the top half of prescribers by volume] writes 25 times as many OxyContin scripts as a prescriber in decile 0-4. In Q1 2013 the majority (52%) of OxyContin primary calls were made to decile 0-4 prescribers. Including the secondary calls, 57% of the primary detail equivalents (PDEs) were made to decile 0-4 prescribers. Best practice in the industry is over 80% of effort on higher value prescribers.”

302. McKinsey concluded: “Given that there are 14,000 uncalled physicians in deciles 5-10, there is significant opportunity to shift calls to higher potential prescribers.”¹⁶⁵

303. McKinsey pointed to a “true physician example” in Wareham, Massachusetts, who wrote 167 more OxyContin prescriptions after Purdue sales reps visited him.¹⁶⁶

¹⁶² MCK-MDL2996-0364024


¹⁶³ MCK-MDL2996-0364267

¹⁶⁴ *Id.*

¹⁶⁵ MCK-MDL2996-0187168 / PPLP004409892

¹⁶⁶ PPLPC012000437356

True physician example



Specialty	Anesthesiology	
Location	Wareham, Massachusetts	
Market Decile	8	

	12 months ending March 2012	12 months ending March 2013
Calls made on physician	0 P1 1 P2	18 P1 1 P2
OxyContin scripts written during 2 nd half of year	177	344

Graphic from McKinsey presentation recommending targeting high prescribers

304. To slow or reverse the decline in OxyContin sales, McKinsey recommended a shift to “value deciles,” which purported to weigh prescribers according to factors including overall opioid prescriptions, including the number of branded versus generic prescriptions; prescriber rules in place limiting sales calls; managed care access; and the number of the prescribers new to brand prescriptions, including new opioid patients and switches from other opioid products.¹⁶⁷ The cumulative effect of the value rankings was to shift detailer emphasis onto the highest-volume prescribers. Further, McKinsey’s analysis found that the highest-volume prescribers were themselves most influenced by detail visits.

305. Purdue moved quickly to do as McKinsey advised. All sales representatives received a memo on December 23, 2013, identifying how to select “SuperCore” prescribers, or the top ten targets,¹⁶⁸ in their territory according to the E2E high prescribing principles and required that each SuperCore prescriber be visited at least twice a month.¹⁶⁹ [REDACTED]

[REDACTED]

¹⁶⁷ PPLPC022000646874

¹⁶⁸ MCK-MDL2996-0316833

¹⁶⁹ PURCHI-000005915

As part of these changes, McKinsey's plan involved *more* minimum sales calls overall.¹⁷¹

306. [REDACTED]

[REDACTED] who later plead guilty to criminal charges related to an opioid drug ring. The prescriber also surrendered his license to practice after an Ohio Medical Board investigation revealed that he prescribed excessive and dangerous combinations of opioids and muscle relaxers and that he prescribed opioids to a patient who complained of headaches and others who showed signs of addiction.¹⁷² The same prescriber received at least sixty visits from Purdue from mid-2013 through 2016.¹⁷³

307. [REDACTED]

[REDACTED] The doctor, who worked at a family practice, was charged with involuntary manslaughter, Medicaid fraud, drug trafficking, grand theft, and other offenses.

308. [REDACTED]

[REDACTED]¹⁷⁴ In 2018, the Drug Enforcement Administration issued an Order to Show Cause and Immediate Suspension Order to Dr. Khan-Jaffrey over concerns that her DEA registration "constituted an imminent danger to the public health and safety," finding she prescribed opioids without a legitimate medical purpose and disregarded urine screens indicating abuse and

¹⁷⁰ PPLPC022000686986

¹⁷¹ MCK-MDL2996-0187168

¹⁷² https://www.cnhinews.com/article_91ffac58-1b32-11e8-b264-6b34793bf5c3.html

¹⁷³ Public information about visits at which a payment was made is available for this time period through "Open Payments."

¹⁷⁴ PPLPC014000257127

diversion.¹⁷⁵ Dr. Khan-Jaffrey's DEA registration was fully revoked on July 28, 2020.¹⁷⁶ Dr. Louis Spagnoletti, of Marlton, New Jersey, [REDACTED] lost his state license to prescribe controlled substances in 2018.¹⁷⁸ Similarly, Dr. Vivienne Matalon, a Decile 10 prescriber from Cherry Hill, New Jersey, [REDACTED] went on to lose her license in 2018 as well, for allegedly receiving kickbacks to prescribe the fentanyl drug Subsys to three patients, including one that died.¹⁸⁰

309. Another prescriber, Dr. Damon Cary of Wilmington, Delaware, [REDACTED] received an emergency suspension order in 2019 after prescribing controlled substances, including opioids, to undercover officers without performing any medical examinations.¹⁸² Dr. Eva Dickinson, of Harrington, Delaware, [REDACTED] was arrested on marijuana charges in 2016 and had her license suspended in 2017 for sharing drugs, including opioids, with her patients.¹⁸⁴

310. Dr. Michael Cozzi of Fort Wayne, Indiana, [REDACTED] had his medical license suspended in 2016, where he had prescribed more controlled substances than any other Indiana prescriber, with over two million doses of oxycodone, seeing ninety to 100 patients a day.¹⁸⁵ Dr. Jamie Gurrero,

¹⁷⁵ <https://www.federalregister.gov/documents/2020/07/29/2020-16387/kaniz-f-khan-jaffery-md-decision-and-order>

¹⁷⁶ *Id.*

¹⁷⁷ PPLPC014000257127

¹⁷⁸ <https://patch.com/new-jersey/moorestown/state-suspends-doctor-accused-illegally-prescribing-opioids>

¹⁷⁹ PPLPC014000257127

¹⁸⁰ <https://nj.gov/oag/newsreleases18/pr20180504d.html>

¹⁸¹ PPLPC014000257130

¹⁸² <https://www.delawareonline.com/story/news/health/2019/08/05/doctor-prescribed-opioids-undercover-cops-failed-follow-protocol/1920386001/>

¹⁸³ PPLPC014000257130

¹⁸⁴ <https://www.delawareonline.com/story/news/health/2017/01/19/doctors-license-suspended-delaware-maryland/96779080/>

¹⁸⁵ <https://www.wane.com/news/fort-wayne-pain-doctors-medical-license-suspended/> (He later died in a tractor accident, <https://www.journalgazette.net/news/local/police-fire/20180816/tractor-accident-kills-pain-doctor>)

1 [REDACTED]
 2 [REDACTED] was sentenced to 100 months in prison in 2016 after pleading guilty
 3 to unlawful distribution or dispensing of controlled substances, health care fraud, conspiracy, and
 4 money laundering.¹⁸⁷

5 311. [REDACTED]
 6 [REDACTED]

7 [REDACTED] Misrepresentations to these prescribers were especially insidious
 8 because they were aimed at general practitioners who lack the time and expertise to closely manage
 9 higher-risk patients on opioids.

10 312. McKinsey also urged, consistent with continually refining its granular approach,
 11 that sales representatives devote two-thirds of their time to selling OxyContin and one-third of their
 12 time selling Butrans, another Purdue opioid product. Previously, the split had been fifty-fifty.

13 2. Circumventing Safeguards Against Abuse and Diversion

14 313. Project Turbocharge also involved a granular analysis of Purdue's individual sales
 15 channels. In its August 8, 2013, report to the Purdue board, McKinsey also attributed the decline
 16 in OxyContin sales to safeguards to limit suspicious opioid sales. McKinsey informed Purdue that
 17 "[t]he retail channel, both pharmacies and distributors, is under intense scrutiny and direct risk."
 18 "There are reports of wholesalers stopping shipments entirely to an increasing number of
 19 pharmacies," "[m]any wholesalers are also imposing hard quantity limits on orders based on prior
 20 purchase levels," and "[p]harmacy chains are implementing guidelines for which patients can fill
 21 opioid prescriptions[.]"¹⁸⁸

22 314. For instance, McKinsey recommended that Purdue circumvent pharmacies entirely
 23 with a mail order program because enforcement by federal regulators was decreasing OxyContin
 24
 25
 26

27 ¹⁸⁶ PPLPC014000257130

28 ¹⁸⁷ <https://www.justice.gov/usao-wdky/pr/kentuckiana-anesthesiologist-sentenced-100-months-unlawful-distribution-controlled>

¹⁸⁸ MCK-MAAG-0024297

1 dispensing through Walgreens. McKinsey informed the Sacklers that “[d]eep examination of
 2 Purdue’s available pharmacy purchasing data shows that Walgreens has reduced its units by 18%.”
 3 Further, “the Walgreens data also shows significant impact on higher OxyContin dosages.”¹⁸⁹

4 315. In order to counter these perceived problems, McKinsey suggested that Purdue’s
 5 owners lobby Walgreens specifically to increase sales and circumvent the safeguarding sales limits.
 6 It also suggested the establishment of a direct-mail specialty pharmacy so that Purdue could
 7 circumvent Walgreens and sell directly to Walgreens’ customers. Finally, McKinsey suggested the
 8 use of opioid savings cards distributed in neighborhoods with Walgreens locations to encourage
 9 the use of Purdue’s opioids despite Walgreens actions.
 10

11 316. McKinsey’s initiative also included ways to circumvent these safeguards. McKinsey
 12 recommended that the sales force distribute vouchers and “starter kits” for patients who faced co-
 13 pays for OxyContin prescriptions.¹⁹⁰ In particular, McKinsey recommended dispensing vouchers
 14 to outlets of a specific large national pharmacy chain where prescriptions and OxyContin
 15 inventories were down.¹⁹¹ This chain, as part of its own settlement with the Drug Enforcement
 16 Administration, had removed pharmacist bonuses for dispensing opioids.¹⁹²
 17

18 3. Incentivizing Opioid Sales

19 317. McKinsey’s “turbocharging” plan also had other elements. [REDACTED]
 20 [REDACTED]
 21 [REDACTED]
 22 [REDACTED]
 23 [REDACTED]
 24 [REDACTED]
 25

26 ¹⁸⁹ *Id.*

27 ¹⁹⁰ MCK-MDL2996-0290827.

28 ¹⁹¹ MCK-MDL2996-0041646.

¹⁹² MCK-MDL2996-0104431; MCK-MDL2996-0041646.

¹⁹³ PPLPC012000437346.

¹⁹⁴ *Id.*

ix. **McKinsey’s Efforts Triple OxyContin Sales**

318. In 2013, despite significant headwinds, with marketing activities turbocharged, OxyContin sales peaked. The restrictions on Purdue’s sales and marketing methods contained in the Corporate Integrity Agreement should have resulted in fewer overall OxyContin sales; the guilty plea identified a specific segment of existing OxyContin sales that were illegitimate and should thus cease. All else being equal, OxyContin sales should have decreased to account for the successful elimination of improper sales. In fact, OxyContin sales did decrease in the immediate aftermath of the 2007 guilty plea.

319. And within five years, however, OxyContin sales would triple. McKinsey is responsible for the strategy that accomplished this. It presented specific plans to Purdue, which Purdue adopted and spent hundreds of millions of dollars implementing. The result: a final spasm of OxyContin sales before the inevitable decline of the drug.¹⁹⁵

320. The Purdue McKinsey collaboration was a spectacular success. Between the 2008 and 2016, Purdue distributed in excess of \$4 billion to the Sackler family, with \$877 million distributed in 2010 alone.

321. These distributions would not have been possible without the McKinsey’s work dramatically increasing OxyContin sales.

322. The Sacklers were aware of the value McKinsey provided: on December 2, 2013, CEO John Stewart informed Kathe Sackler and Vice President of Sales and Marketing Russell Gasdia Project Turbocharge “was already increasing prescriptions and revenue.” Crucially, these results were already being realized *before* the strategy was fully deployed as the theme of the 2014 National Sales Meeting. Stewart elaborated to Sackler that “trends are more positive than was the

¹⁹⁵ On February 10, 2018, Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin sales force.

1 case a few months back, and when the E2E Project (the changes arising out of the McKinsey
2 analysis) is fully implemented there will certainly be additional increases.”¹⁹⁶

3 323. Later that month, [REDACTED]
4 [REDACTED]
5 [REDACTED]

6 324. McKinsey’s contributions to Purdue’s growth after 2007 are remarkable. OxyContin
7 sales should have naturally declined; the Department of Justice identified OxyContin sales that
8 were illegitimate because of Purdue’s conduct, and the Inspector General of the Department of
9 Health and Human Services entered into a Corporate Integrity Agreement whereby Purdue was
10 monitored to assure that those sales did not continue.

11 325. In 2007, the year of Purdue’s guilty plea, net sales of OxyContin totaled
12 approximately \$1 billion.¹⁹⁸

13 326. The guilty plea “did little to stem Purdue’s blistering growth rate.” In fact, by 2010,
14 after McKinsey was advising Purdue on how to maximize sales, OxyContin sales exceeded \$3
15 billion: a *tripling* of revenue from OxyContin sales.¹⁹⁹

16 327. Under McKinsey’s guidance, OxyContin sales would reach their all-time peak in
17 2013, the year McKinsey proposed, and Purdue adopted, Project Turbocharge.²⁰⁰ That OxyContin
18 sales peaked in 2013 is especially notable, given that *overall* opioid prescriptions had *already*
19 *peaked* three years earlier, in 2010.²⁰¹ McKinsey’s efforts added a final boost to OxyContin sales
20 before the eventual unraveling, and Purdue’s decision, in the end, to cease marketing the drug.
21

22
23 ¹⁹⁶ PPLPC012000454422

24 ¹⁹⁷ PPLPC012000457292

25 ¹⁹⁸ See David Crow, *How Purdue’s ‘one-two’ punch fueled the market for opioids*, Financial Times, September 9, 2018,
26 available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

27 ¹⁹⁹ *Id.*

28 ²⁰⁰ Phil McCausland and Tracy Connor, *OxyContin maker Purdue to stop promoting opioids in light of epidemic*, NBC News, February 10, 2018, available at: <https://www.nbcnews.com/storyline/americas-heroin-epidemic/oxycontin-maker-purdue-stop-promoting-opioids-light-epidemic-n846726>

²⁰¹ Gery P. Guy Jr, *at al.*, *Vital Signs: Changes in Opioid Prescribing Patterns in the United States, 2006-2015*, Centers for Disease Control and Prevention, July 7, 2017, available at: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm>

1 328. Project Turbocharge was a continuing success. [REDACTED]
2 [REDACTED] and Chief Financial Officer Edward
3 Mahoney reported to the Purdue board that the effort “has resulted in significant improvement.” [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]

7 329. McKinsey was paid handsomely: it received more than [REDACTED] for its work for
8 Purdue from 2008 to 2013 alone.²⁰⁴ In pursuit of these profits, McKinsey continued to help Purdue
9 grow opioid sales even after Purdue reached a 2015 Assurance of Discontinuance with New York
10 arising out of an investigation concerning its Abuse and Diversion Detection program and media
11 coverage highlighted its lack of attention to diversion control. McKinsey’s own work elsewhere
12 identified “reducing prescribing” as among the efforts to combat the opioid epidemic and also
13 showed that opioid prescribers were frequently writing prescription for patients with known risks
14 of abuse. Still, McKinsey continued to work to help opioid manufacturers increase opioid sales,
15 including through Purdue’s deceptive marketing campaign.
16

17 330. By 2014, according to Purdue, there were 5.4 million OxyContin prescriptions
18 written, 80% for twelve-hour dosing. Of those prescriptions, more than half were for doses greater
19 than sixty milligrams per day.
20

21 331. The Sackler family has withdrawn over \$10 billion from Purdue since 2008,
22 including \$1.7 billion in 2009 alone. These distributions were made possible by McKinsey’s
23 services and came at the expense of a deepening national opioid crisis.

24 **e. McKinsey’s Opioid-Related Work with Other Clients.**
25
26
27

28 ²⁰² PPLPC037000159028

²⁰³ PPLPC014000263961

²⁰⁴ PPLPC029000547371

332. Part of the unique value McKinsey provides is its deep knowledge of its clients' competitors, often because it counts those same competitors as its clients. McKinsey generally does not disclose to its clients its work for their competitors.

333. The opioid industry was no different. Indeed, McKinsey specifically worked to

[REDACTED]

[REDACTED]

[REDACTED]

i. Endo

334. While McKinsey was working for Purdue, McKinsey was also working for Endo Pharmaceuticals. Arnab Ghatak was a principal McKinsey partner on both accounts at the same time.²⁰⁶ There was additional overlap between the McKinsey teams staffed to Purdue and Endo, including McKinsey partners Nicholas Mills and Laura Moran. After all, these particular consultants had granular expertise in the specific subject-matter relevant to these opioid manufacturers. That subject-matter expertise is a compelling reason why McKinsey is hired in the first place. McKinsey advised both Endo and Purdue how to maximize the sales of their branded opioid products—Belbuca (Buprenorphine), Butrans (Buprenorphine), Opana (Oxymorphone), and OxyContin (Oxycodone) —all at once.

1. New Blues

335. Like Purdue, Endo was historically a pharmaceutical manufacturer focused on the pain market. Like Purdue, Endo relied on opioid sales for a significant portion of its business. As a

²⁰⁵ MCK-MDL2996-0041741.

²⁰⁶ Ghatak's familiarity with both Endo and Purdue is perhaps one reason why, on April 3, 2014, Ghatak was placed in charge of analyzing a proposed *partnership* between Purdue and Endo to sell opioids. Luran Moran described the "partnership workstream" that McKinsey was then performing for Purdue to identify ways for Purdue to obtain near-term growth. She stated that Purdue and McKinsey "agreed the partnerships workstream should include the top 3 potential partners (Valeant, Endo and Pfizer for now). And for each what assets each partner would bring and what growth (most importantly) would the deal bring. Arnie [Ghatak] and Phil to work out Endo and Valeant, John G and Raul to do Pfizer tomo." MCK-MDL2996-0421790.

1 matter of fact, Endo's history with opioids predates the Sacklers' ownership of Purdue. In 1950,
 2 Endo's predecessor, Intravenous Products of America, Inc., launched Percodan, an
 3 Oxycodone/Aspirin tablet. In 1971, Endo, then owned by E.I. du Pont de Nemours and Company
 4 ("DuPont"), launched Percocet, another oxycodone-based tablet.²⁰⁷

5
 6 336. In 1997, Endo separated from DuPont to become a standalone private company
 7 retaining Percodan and Percocet.²⁰⁸ In 2000, as the result of an acquisition, the company became
 8 public.²⁰⁹

9 337. In 2006, Endo launched its own branded oxymorphone products, Opana and Opana
 10 ER.²¹⁰ With the legacy assets of Percodan and Percocet, Endo's business had always been focused
 11 on opioid sales. Oxymorphone is not a new opioid, and Opana was not Endo's first oxymorphone
 12 product. It was first synthesized more than a century ago in Germany. Endo began selling it in the
 13 United States in 1959 under the name Numorphan.

14
 15 338. Numorphan was referred to as "blues," after the color of the 10mg pills. It delivered
 16 a more euphoric high than heroin, according to some. In 1974, the National Institute on Drug Abuse
 17 noted in its "Drugs and Addict Lifestyle" report that Numorphan was popular as an abused drug
 18 for its quick and sustained effect.²¹¹ By 1979, Endo withdrew Numorphan from the market. Upon
 19 information and belief, [REDACTED]
 20 [REDACTED]
 21 [REDACTED]

22
 23
 24 ²⁰⁷ <https://www.endo.com/about-us/history#fragment-25>

25 ²⁰⁸ <https://www.endo.com/about-us/history#fragment-24>

26 ²⁰⁹ <https://www.endo.com/about-us/history#fragment-21>

27 ²¹⁰ <https://www.endo.com/about-us/history#fragment-15>

28 ²¹¹ John Fauber & Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015),
 available at: <https://www.medpagetoday.com/psychiatry/addictions/51448>

²¹² EPI000443330 ("

ENDO-OPIOID-MDL-06246554

1 339. The memory of the 1970s Numorphan addiction crises did not fade quickly. In 1989,
2 the film *Drugstore Cowboy* featured Matt Dillon as an addict in the 1970s who robs drug stores to
3 obtain drugs to sell in order to finance his opioid dependency.²¹³ In one scene, an addict asks
4 Dillon's character if he has any "blues." Dillon's character explains that "blues" are increasingly
5 hard to find, and offers to sell morphine sulfate to an addict instead. The addict explained that he
6 much preferred the Numorphan, but settled for the morphine.²¹⁴

8 340. With the launch of Opana, Endo decided it was time for history to repeat itself. After
9 Opana's approval in 2006, Endo solidified its position as a pain specialist among manufacturers.
10 By 2012, opioid sales accounted for approximately \$403 million of Endo's \$3 billion in revenue,
11 more than 10%. From 2010 to 2013, total Opana ER revenue alone exceeded \$1.1 billion.

12 341. Opana and Numorphan were both oxymorphone. The brand name was the only thing
13 that changed. What Endo removed from the market in 1979 due to abuse concerns, it re-introduced
14 27 years later. After 2006, Opana was on occasion referred to as "blue heaven," or, more to the
15 point, "new blues."²¹⁵

17 342. In 2017, Endo would once again remove its branded oxymorphone product from the
18 market, and for the same reason. Endo's abuse-deterrent formulation of Opana was removed at the
19 request of the FDA due to acute concerns about its abuse potential.

20 343. In addition to its branded products, Endo, through subsidiaries Qualitest
21 Pharmaceuticals, Inc. and, after its acquisition in 2015, Par Pharmaceuticals, also manufactured
22 generic versions of oxycodone, oxymorphone, hydromorphone, and hydrocodone. Over the course
23 of McKinsey's relationship with Endo, McKinsey would repeatedly advise Endo how to maximize
24 its generics business in addition to sales of Endo's branded opioids.

27 _____
28 ²¹³ See <https://www.imdb.com/title/tt0097240/>; <https://www.bionity.com/en/encyclopedia/Oxymorphone.html>

²¹⁴ Scene from *Drugstore Cowboy*, available at: https://www.youtube.com/watch?v=TksvZdrx9_A

²¹⁵ https://www.deadiversion.usdoj.gov/drug_chem_info/oxymorphone.pdf

2. Old Friends

344. McKinsey's relationship with Endo began as early as in 2006, the same year as the Opana launch.

345. McKinsey's earliest known work with Endo concerned the launch of Opana in Europe, but its relationship with Endo would expand to encompass all aspects of Endo's business, including corporate organization and resource allocation, the launch of a new branded Buprenorphine product, and sales force optimization efforts for Endo's branded and generic opioid products.

346. In 2007, McKinsey was shaping overall corporate strategy at Endo. In a presentation to Endo's board of directors in May of that year [REDACTED]

347. McKinsey's partnership with Endo would last more than a decade, and, like its relationship with Purdue, is an exemplary example of the transformational relationship in action.

348. In some ways, the McKinsey's relationship with Endo was even more tightknit and companionable than with Purdue. For instance, no one at Purdue previously worked for McKinsey. In early 2013, Rajiv de Silva, previously a leader of McKinsey's PMP group, was appointed CEO of Endo. At Endo, McKinsey was now advising an old friend, one of its previous senior partners.²¹⁷

²¹⁶ ENDO-OPIOID_MDL-02899510.

²¹⁷ See "Rajiv De Silva Named President and CEO of Endo Health Solutions," Press Release dated February 25, 2013, available at: <https://investor.endo.com/news-releases/news-release-details/rajiv-de-silva-named-president-and-ceo-end-health-solutions> ("Earlier in his career, he was a Principal at McKinsey & Company, where he served as a member of the partnership group that led the global Pharmaceuticals and Medical Products practice.")

1 349. As de Silva himself explained, [REDACTED]

2 [REDACTED]

3 [REDACTED]

4

5 350. Under de Silva, Endo relied more heavily on McKinsey than ever before. McKinsey

6 consultants interacted directly and often *exclusively* with de Silva. McKinsey was so close to the

7 Endo CEO that it could intervene in direct reporting from one of de Silva's deputies.²¹⁹ It is as if

8 McKinsey had insinuated itself as a shadow layer of bureaucracy within Endo.

9 351. McKinsey maintained weekly performance review meetings with de Silva and

10 senior Endo management. In these meetings, granular weekly sales data was reviewed for each of

11 Endo's branded products, including Opana.²²⁰

12 352. McKinsey advised both Purdue and Endo contemporaneously for more than a

13 decade. With each client, the goal was the same: to maximize opioid sales. The work McKinsey

14 performed for each client was so similar that there was routinely confusion internally about whether

15 a specific project or task to perform was for Endo or Purdue.²²¹

16

17 353. Despite McKinsey's emphasis on confidentiality, the fact that McKinsey repeats its

18 work from one client to the next is well-known to the client. Indeed, it is part of the justification in

19 hiring McKinsey in the first place. McKinsey can tell you what everyone else is doing. [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23

24 _____

²¹⁸ ENDO-OPIOID-DEPMAT-000047877 at pg. 320:22 – 321:3.

25 ²¹⁹ See MCK-MDL2996-0405502 (Email from Ghatak to de Silva, stating that it "would be great for you to push Blaine

26 and Bob [both Endo employees] on why there are no slides showing the metrics on field call attainment . . . there was

an explicit agreement to track them. Setting the expectation that you want them included would really help").

²²⁰ MCK-MDL2996-0062712.

27 ²²¹ In response to an internal email from Craig MacKenzie to other McKinsey consultants seeking "expert input on

28 labels for abuse deterrent formulations" in conjunction with McKinsey's work on the Belbuca launch (discussed *infra.*),

McKinsey consultant Jeff Smith replied, "Craig – is this for Purdue or Endo? If for Endo, I am conflicted." MCK-MDL2996-0383805.

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]²²²

4

5 **3. Opana**

6 354. McKinsey's earliest known work with Endo [REDACTED]

7 [REDACTED] In a November 22, 2006, presentation²²³ entitled [REDACTED]

8 [REDACTED] McKinsey advised [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 355. McKinsey noted, [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 356. McKinsey also [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23

24

25 ²²² ENDO-OPIOID-MDL-07619243.

26 ²²³ The McKinsey presentation was [REDACTED]

[REDACTED] NDO-OPIOID_MDL-02936031. By 2007,

McKinsey had [REDACTED]

[REDACTED] ENDO-OPIOID_MDL-06078889. Endo acquired Penwest in 2010. "Endo Pharmaceuticals Agrees to Acquire Penwest Pharmaceuticals," Fierce Biotech, August 10, 2010, *available at*: <https://www.fiercebiotech.com/biotech/endo-pharmaceuticals-agrees-to-acquire-penwest-pharmaceuticals>

28 ²²⁴ ENDO-OPIOID_MDL-02936031.

²²⁵ *Id.*

1 [REDACTED]
2 [REDACTED]
3 357. McKinsey advised [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]

8 358. McKinsey [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 359. Within a few years of its introduction in the United States, abuse of the drug became
16 widespread. Endo then sought to introduce a reformulated version of Opana that it could market as
17 abuse-deterrent by introducing a tamper-resistant coating to the pill.

18 360. In December 2011, Endo obtained FDA approval for a new formulation of Opana
19 ER with the coating that Endo claimed was crush-resistant. The following month, however, the
20 FDA told Endo that it could not market Opana ER, even after the reformulation, as abuse-deterrent.

21 361. Endo “did not submit any new clinical safety or efficacy data” as part of its
22 application, but rather relied entirely on the “bioequivalence” of the new and old formulations of
23 Opana. Obtaining approval of reformulated Opana ER on this basis allowed Endo to rely on the
24 safety and efficacy of the original version of the drug as the basis for approval of the reformulated
25
26

27 _____
28 ²²⁶ *Id.*

²²⁷ *Id.*

²²⁸ *Id.*

1 version.²²⁹ The FDA found that such promotional claims “may provide a false sense of security
 2 since the product may be chewed and ground for subsequent abuse.” In other words, Opana ER
 3 was still crushable. In December 2011, Endo admitted that “[i]t has not been established that this
 4 new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction.”²³⁰

5
 6 362. In 2013, an Endo training module directed key opinion leaders to instruct prescribers
 7 that OPANA ER with INTAC is the only oxymorphone designed to be “crush-resistant,” and
 8 advised the key opinion leaders to state during their speeches that “[t]he only way for your patients
 9 to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe OPANA
 10 ER with INTAC.”²³¹ The speakers were advised to stress that generic versions of Oxymorphone
 11 “are not designed to be crush-resistant.”

12
 13 363. These abuse-deterrent attributes of the reformulation—the very characteristics
 14 McKinsey and Endo touted as a reason to prescribe Opana—were a sham. The reformulation was
 15 designed to prevent the pill from being crushed and snorted through the nose. It did not prevent
 16 intravenous use, however. The result was that many users already dependent of Opana began using
 17 needles to inject the drug for the first time. As an internal Endo email put it, [REDACTED]
 18 [REDACTED]

19
 20 364. Jeff, a veteran of the war in Iraq, explained the process. Jeff first became dependent
 21 on Percocet and Opana after returning from Iraq, where his back was injured when his Humvee
 22 rolled over in 2008. After being prescribed opioids for his back pain, Jeff became dependent, and
 23

24
 25 ²²⁹ Intervenor Impax Laboratories, Inc.’s (1) Cross-Motion to Dismiss; or, in the Alternative, (2) Opposition to
 26 Plaintiff’s Motion for a Preliminary Injunction, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.* (“Impax Br.”), No. 1:12-cv-01936 Doc. 18 at 7 (D.D.C. Dec.9, 2012); *see also* FDA Summary Review for
 27 Regulatory Action, NDA 201655 (Dec. 9, 2011) (stating that “[n]o new safety data were included in this submission”
 28 and “[n]o efficacy studies were submitted in this application.”).

²³⁰ Endo Dec. 12, 2011 News Release; Ex. A to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 Doc. 18-2 (D.D.C. Dec. 9, 2012).

²³¹ EPI000421543.

²³² END00010732.

1 began using Opana by snorting it. Endo then introduced the reformulated abuse-deterrent version
 2 of Opana in 2012. “[A]nd then they reformulated them,” he said, referring to the Opana pills. “And
 3 the only way you could really do them is inject them because if you actually swallow them, it – you
 4 – they really don’t do nothing.”²³³

5
 6 365. Jeff and his companion Joy showed the journalist how the drug was used. “You want
 7 to see how to cook it?” Jeff asked. He and Joy then proceeded to place a portion of an Opana pill
 8 on piece of aluminum and heat it with a lighter. “Right away, I can start to see this hard, white
 9 coating just kind of floating off the piece of the pill. It looks like plastic,” described the journalist
 10 witnessing the process.²³⁴

11
 12 366. Joy explained how the abuse-deterrent coating, once melted, was discarded by using
 13 the filter of a cigarette: “Now you see the coating of – all that mess laying there still? . . . That’s
 14 what the filter’s for.”²³⁵ The journalist described what then took place:

15 And Joy puts that cigarette filter into the liquid, and they Joy, Jeff and another guy
 16 each take turns with their needles, sticking it into the filter and pulling the liquid
 17 through. Joy and Jeff turn their back to me while they inject. And then it just gets
 really, really quiet.

18 367. Joy couldn’t conceive of the position she was in. A nurse, she hurt her back at work
 19 and began taking prescription pain medication. She began taking the pills by mouth, and later began
 20 to snort them. Dependency began. But she told herself, “I’d never ever would use a needle, never.
 21 I’m never going to do that.”²³⁶

22
 23
 24
 25
 26

 27 ²³³ Kelly McEvers, “Opioid Epidemic Sparks HIV Outbreak in Tiny Indiana Town,” NPR, March 31, 2016, *available*
 at: <https://www.npr.org/2016/03/31/472577254/opioid-epidemic-sparks-hiv-outbreak-in-tiny-indiana-town>

28 ²³⁴ *Id.*

²³⁵ *Id.*

²³⁶ *Id.*

1 368. After Opana’s reformulation, Joy began using it intravenously. “I started using the
2 needle about – it was around the 6th of February,” she said. “I’m so ashamed I pack so much
3 shame, and I’m going to cry I pack so much shame from it. I do.”²³⁷

4 369. Endo’s 2012 reformulation of Opana caused outbreaks of HIV in populations of
5 intravenous Opana users. In Austin, Indiana, where Jeff and Joy resided, Opana was linked to an
6 outbreak of at least 200 HIV cases in a town with a population of 4,500.²³⁸

7 370. Intravenous use of reformulated Opana has also been associated with outbreaks of
8 Hepatitis C and Thrombotic Thrombocytopenic Purpura (“TTP”).²³⁹ The concerns even reached
9 Wall Street, where an analyst asked Endo about a TPP outbreak in Tennessee associated with Opana
10 ER. Endo assured the analyst that the outbreak was, like the outbreak in Indiana, in “a very, very
11 distinct area of the country.”
12

13 371. Endo was well aware of these problems. [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19

20 372. In June of 2013, McKinsey [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25

26 _____
27 ²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ “Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012,” *Morbidity and Mortality Weekly Report* (Jan. 11, 2013).

²⁴⁰ ENDO00260151.

1 [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 [REDACTED]
 5 [REDACTED]
 6 373. McKinsey indicated [REDACTED]
 7 [REDACTED]
 8 [REDACTED]
 9 [REDACTED]
 10 [REDACTED]
 11 [REDACTED]
 12 [REDACTED]

13 374. In addition to being neither feasible nor safe/ethical, the study was beside the point.
 14 An insufflation study is meant to determine the abuse characteristics of a drug when used nasally—
 15 i.e., by snorting the drug.²⁴⁴ The relevant concern for Opana's reformulated version was *injection*,
 16 not insufflation.

17 375. But the insufflation study worked for Purdue. Going forward, McKinsey suggested
 18 [REDACTED]
 19 [REDACTED]

20 376. As the preceding paragraphs make clear, Endo and McKinsey were laser-focused
 21 on maximizing overall sales of Endo products, and decidedly *not* on concerns over their actual
 22 abuse potential or the appropriate *size* of the market for these products, given evident, longstanding,
 23 and ever-present concerns about their abuse. To the point, McKinsey regarded concerns about
 24 [REDACTED]

25 ²⁴¹ EPI002107711.

26 ²⁴² *Id.*

27 ²⁴³ *Id.* (emphasis added).

28 ²⁴⁴ See General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products, FDA Center for Drug Evaluation and Research, November 2017, available at: <https://www.fda.gov/files/drugs/published/General-Principles-for-Evaluating-the-Abuse-Deterrence-of-Generic-Solid-Oral-Opioid-Drug-Products-Guidance-for-Industry.pdf>

²⁴⁵ EPI002107711.

1 opioid abuse only as a means by which its clients could introduce *differentiated* products (i.e., those
 2 with purported abuse-deterrent or tamper-resistant features) to continually perpetuate overall
 3 opioids sales for their clients. In all instances, the parties desired for the size of that overall opioids
 4 market to grow in line with the introduction of “differentiated” products like a reformulated Opana.

5
 6 377. Endo’s purported concern about deterring abuse of its drugs was laid bare as farce
 7 by a particularly striking decision: to continue to sell the old formulation of Opana despite touting
 8 the notion that the old formulation was purportedly dangerous in ways that the new formulation
 9 was not. Endo [REDACTED]

10 [REDACTED]
 11
 12 378. Endo not only continued to distribute original Opana for nine months after the
 13 reformulated version became available, it declined to recall original Opana ER despite its
 14 dangers.²⁴⁷ In fact, Endo also claimed in September 2012 to be “proud” that “almost all remaining
 15 inventory” of the original Opana ER had “been utilized.”²⁴⁸

16 379. In June 2013, an Endo employee informed the McKinsey consultants of a [REDACTED]
 17 [REDACTED]
 18 [REDACTED]
 19 [REDACTED]
 20 [REDACTED]
 21 [REDACTED]

22 4. Belbuca: Endo’s Answer to Butrans

23 380. Buprenorphine is another differentiated product. Opioid manufacturers began to
 24 introduce Buprenorphine products to the market after the introduction of OxyContin, Opana, and
 25

26 _____
 27 ²⁴⁶ ENDO-OPIOID-MDL-02324795.

²⁴⁷ Impax Br. at 1.

²⁴⁸ *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

²⁴⁹ ENDO-OR-CID-00400235 (emphasis added).

other branded opioids long-known to have abuse and dependency problems. Buprenorphine products were marketed as purportedly less dangerous than products such as OxyContin or Opana.

381. Of course, Endo and Purdue continued to assiduously market and sell OxyContin and Opana alongside their Buprenorphine products, and McKinsey worked with each at every step of the way, despite the implicit contradiction in marketing two products at the same time whose point of differentiation is one being *less addictive and dangerous* than the other.

382. For example, on August 13, 2015, McKinsey's Craig MacKenzie circulated a discussion document to Endo and McKinsey staff entitled "Belbuca value proposition," which laid out McKinsey's thoughts on how to differentiate Endo's buprenorphine product from other opioids in the marketplace.²⁵⁰ One point of differentiation McKinsey noted was that OxyContin was commonly abused, while Endo's Belbuca hopefully would not be:²⁵¹

Product strengths

Comparative value propositions against Purdue products

		BELBUCA	OXYCONTIN [®] <small>(HYDROCODONE, NOT CONTROLLED-RELEASE) TABLETS</small>	Hysingla [®] ER
Safety	Abuse deterrence	Perceived due to inherent properties in formulation and molecule	Commonly abused; reformulated as "abuse deterrent" in 2010	Formulated with abuse deterrent properties
	Side effects/tolerability	Good tolerability after titration, low constipation	Average, can be associated with nausea, vomiting, & constipation	Lack of NSAID or tylenol decrease risk of adverse reaction

383. The cognitive dissonance was palpable. At the same time that MacKenzie sent his email differentiating Belbuca, and as described *supra*, McKinsey was *also* maximizing OxyContin sales for Purdue—the opioid it was describing to Endo as commonly abused.

²⁵⁰ MCK-MDL2996-0410742.

²⁵¹ MCK-MDL2996-0006669, at 0006675.

1 384. [REDACTED]

3 [REDACTED] Butrans was Purdue's buprenorphine product.

4 385. Once Butrans was launched at Purdue, McKinsey worked with Endo to create
5 another branded Buprenorphine product to compete with Butrans. These product planning and
6 launch processes are long-term affairs. McKinsey worked with Endo on this project for *four years*
7 before Endo's Belbuca obtained FDA approval.

9 386. McKinsey remained in place at Endo to implement the launch of Endo's
10 Buprenorphine product. The strategic goal of Belbuca—the key to its commercial success—was to
11 convert short acting opioid (“SAO”) users to Belbuca. As McKinsey explained to CEO Rajiv de
12 Silva, “The fundamental question is whether Belbuca will take share from the short-acting
13 opioids.”²⁵²

15 387. Ultimately, Belbuca was not a large commercial success for Endo because it failed
16 to transition a sufficient number of short acting opioid users to the long-acting Belbuca. As the drug
17 underperformed, Endo felt ever more pressure to stimulate sales. John Harlow described one
18 meeting with de Silva on April 8, 2016: “We just got out of the review with Rajiv and clearly our
19 TRx trends are not good and are behind other recently launched pain products . . . the request from
20 Rajiv was to do anything possible that could be implemented ASAP to stimulate RXs.”²⁵³

22 388. By July 6, 2016, McKinsey and Endo were increasingly focused on converting
23 short-acting opioid users. [REDACTED]

25 [REDACTED] Notably, the goal was to increase *overall* buprenorphine prescriptions,

27 ²⁵² MCK-MDL2996-0210158.

28 ²⁵³ MCK-MDL2996-0358973, at 0358975.

²⁵⁴ ENDO-OPIOID_MDL-07264539

1 not only those of Belbuca. The discussion document identified an objective to create “a new
2 treatment paradigm for [Buprenorphine] and Belbuca at the transition between SAO and LAO.”²⁵⁵
3 In order to do so, the discussion group needed to determine “what medical support we need to
4 position Buprenorphine as the best transition from SAO to LAO.”²⁵⁶
5

6 389. McKinsey provided a slide to Endo describing the way that narrative would first be
7 *created* and then exploited for market positioning:²⁵⁷
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27 ²⁵⁵ *Id.*

28 ²⁵⁶ *Id.*

²⁵⁷ MCK-MDL2996-0382731.

Overall timeline for rolling out Belbuca/Bup 'transition' positioning

Q3 – Get the facts in place to tell the story

- Medical Literature Review
- Crafting the overall cross-stakeholder story for Bup. as ideal 'transition'
- Prioritize stakeholders (payers, advocacy groups) for communication

Q4 – Broadcast the story

- Publish national article on Bup transition
- Build out speakers on Bup
- Drive 'can't step through CII' message to payers
- Create pilots with payers/providers (e.g., VA, Geisinger) to prove value

1H 2017 – Create compelling data to accelerate the proof points

- Make progress on RWE/RCT trials (e.g., H2H with Oxy, cancer pain)
- Finalize retrospective studies on abuse
- Health Economics analysis
- Exploration of 'step through Bup' deals with payers (prior to CII LAO)

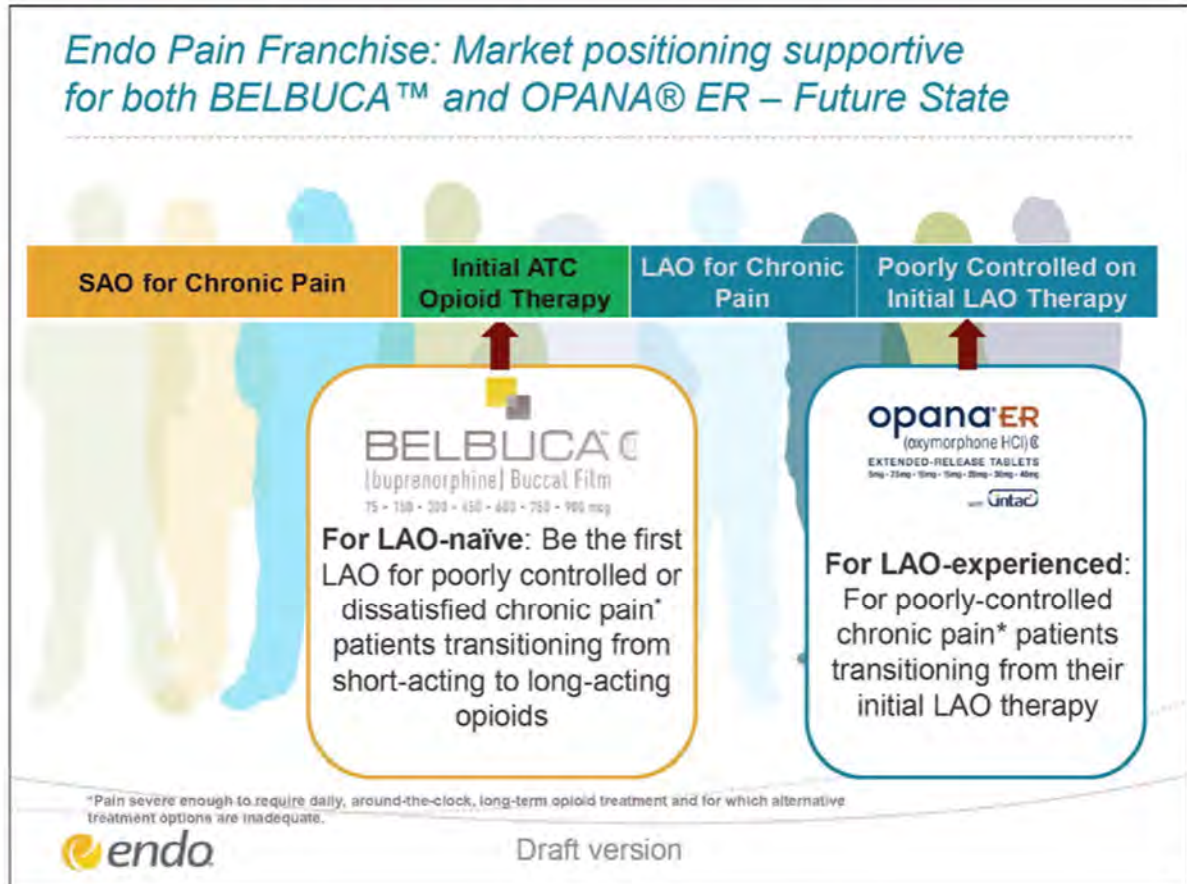
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390. McKinsey and Endo referred to this effort to revive Belbuca sales by promoting buprenorphine as a bridge to long-acting opioid use as a “moonshot.”²⁵⁸ One aspect of this “moonshot” would be that Belbuca (and Buprenorphine, generally) would convert short-acting opioid users to long-acting opioids users of products *other than Buprenorphine*. McKinsey and Endo instead conceived of Belbuca as an “*Initial ATC Opioid Therapy*.” It was to be positioned as “the *first* LAO for poorly controlled or dissatisfied chronic pain patients transitioning from short-

²⁵⁸ MCK-MDL2996-0382412.

acting to long-acting opioids.” Patients could eventually transition from Belbuca to other long-acting opioids, like Opana:²⁵⁹



391. Thus, the overall marketing strategy McKinsey assisted Endo in designing and deploying for Belbuca was designed to transition ever more patients to long-acting opioids. Belbuca could find its market niche as a stepping stone as individuals proceed through the patient funnel from short acting opioid users to longer-term long-acting opioid users. The farther individual proceeds through this funnel, the more the individual is worth.

392. McKinsey also knew that this same pathway that begins with opioid therapy after a serious injury also leads to opioid dependency and addiction. In 2011, McKinsey was working on

²⁵⁹ MCK-MDL2996-0404374, at 0404375.

“Project X.” which was the project to develop a buprenorphine product to compete with Butrans. (Belbuca, in other words, was the result of Project X.) McKinsey described the “opioid dependence treatment pathway” as follows:²⁶⁰

breakthrough thinking, collaboration, customer focus, accountability.

OPIOID DEPENDENCE TREATMENT PATHWAY

- Patient begins opioid therapy following serious injury/surgery
- Patient pain not controlled, dosages increase, patient seeks additional medication options
- Patient referred to pain specialist
- Patient shows up in ER, Clinic or seeks out addictionologist
- Addictionologist – Pain Specialist or Psychiatrist with additional license to prescribe Methadone, Subutex/Suboxone for opioid dependence
- Options
 - Methadone
 - Subutex initiation, followed by Suboxone treatment

Confidential Internal Document. Draft – Not Approved by Management. 13

393. In the same presentation, McKinsey identified the key to a successful launch of a branded Buprenorphine product: “The challenge faced by Endo will not be to gain formulary approval, it will be to gain tier 2 status and *minimize restrictions on prescribing*.”²⁶¹

5. Turbocharging the Sales Force with a Blitz

394. In 2015, a McKinsey team led by Arnab Ghatak proposed to Endo a sales transformation to invigorate Endo’s product sales, including its opioids. At the suggestion of

²⁶⁰ MCK-MDL2996-0131500, at 0131512.

²⁶¹ MCK-MDL2996-0131500, 0131525 (emphasis added).

1 Ghatak, McKinsey used the Purdue Pharma Project Turbocharge model from the previous year as
 2 a template for the Endo proposal.²⁶² Even the PowerPoint presentations used to create the proposal
 3 to Endo were drafted off the Project Turbocharge slides. On June 28, 2015, Sherin Ijaz of McKinsey
 4 emailed Ghatak, Nicholas Mills, and Laura Moran to circulate a draft proposal for an “Endo sales
 5 force transformation” PowerPoint presentation. Ijaz explained, “Laura, I heavily leveraged what
 6 you send (sic) from Purdue as it was all applicable.”²⁶³ All three of the recipients of Ijaz’s email
 7 regarding the Endo proposal had been working on the Purdue account for years.

9 395. Endo [REDACTED]

14 396. Endo’s Vice President & General Manager of its Pain Business Unit, John Harlow,

21 397. The Endo and Purdue proposals were essentially identical sales transformations. The
 22 goals were the same: to maximize sales of opioids. Merely the names were changed. While
 23 McKinsey offered to “turbocharge” Purdue’s sales force, McKinsey proposed a “sales force blitz”
 24 for Endo.²⁶⁷

26 ²⁶² MCK-MDL2996-0075895.

27 ²⁶³ MCK-MDL2996-0070237.

28 ²⁶⁴ ENDO_AAC_00363406.

²⁶⁵ *Id.*

²⁶⁶ *Id.*

²⁶⁷ *E.g.*, MCK-MDL2996-0130803; MCK-MDL2996-0132851.

398. In fact, the names weren't *entirely* changed. [REDACTED]

Overview of our approach: 'Turbocharging the Sales Engine'

- There are **5 key pillars** that should be addressed in the sales transformation effort
 - **Sales strategy and targeting:** Shift from decile-based to workload-based targeting approach provide right support to sales force, and build deep sales analytics capabilities
 - **Effective selling skills:** Mandate field adherence to the target list and compliance with targets
 - **Disciplined sales process:** Increase rep productivity and explore ways to increase time in field
 - **Efficient coverage:** Align resources with highest potential opportunities and consider re-alignment of territories and increasing overall field force size
 - **Behavior & mindset:** Establish performance management system and incentives aligned with corporate objectives, and establish a culture of continual improvement
- Comprehensive sales transformation programs **typically take 9 months**, which we recommend dividing into **three phases: Ready, Run, Refine**
 - **Ready:** Set the groundwork for the sales transformation, including creating leadership buy-in and establishing high-level objectives and targets
 - **Run:** Launch a major field force kickoff explaining the change and vision, followed by district meetings led by field and home office leaders, regional champions, and other support team members
 - **Refine:** Expand the impact to the next level with additional high impact levers such as expanding the field force and re-aligning territories
- There are a number of key **design and execution decisions** that need to be addressed before the sales transformation can begin in full
- We have developed a **14-workstream plan with specific owners** to execute on this vision



2

399. [REDACTED]

²⁶⁸ MCK-MDL2996-0069747, at 0069749. [REDACTED]

1 400. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 401. Upon McKinsey's suggestion, Endo began reallocating sales force resources to
7 Opana from other Endo products such as Sumavel, a migraine medication, and Voltaren, an anti-
8 inflammatory.²⁶⁹ Writing to the McKinsey team, Endo's Alicia Logan stated the joint mission, "I
9 agree that our main goal is to maximize the increased promotional efforts for [Opana ER] without
10 disrupting/sacrificing [Sumavel] or [Voltaren] TRx volume and it appears that we [can] accomplish
11 this with your recommendation of addition another 500 targets."²⁷⁰

12 402. With the Sales Force Blitz underway, Endo received good news in New York. Years
13 prior, Endo had initiated patent litigation against generic manufacturers of Opana ER, arguing that
14 the generic versions of the drug infringed on Endo's patents. In part because of the perceived
15 impending loss of exclusivity, Endo had in recent years allocated its sales force capacity away from
16 Opana and to other Endo products.

17 403. On August 14, 2015, Endo received a favorable initial ruling declaring that the
18 generic versions of Opana violated Endo's patents, and enjoined their further sale. The ruling
19 provided additional patent exclusivity for Opana, and Endo was keen to exploit its advantage.
20

21 404. That afternoon, [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

26

27 ²⁶⁹ MCK-MDL2996-0409466.

28 ²⁷⁰ MCK-MDL2996-0409436, at 0409437 (sic).

²⁷¹ ENDO-OPIOID_MDL-02279530.

1 405. The following week, Harlow wrote to the McKinsey team working for Endo to focus
 2 their attention on Opana ER. “Now with our litigation victory from last week, plus our UHC
 3 opportunity, there is an increased need to increase FF support to drive Sep-Dec business. . . . With
 4 this win, I am now willing to go broader with OER targeting.”²⁷²

5 406. McKinsey and Endo proceeded to design and implement retargeting strategies to
 6 boost Opana sales in late 2015.
 7

8 **ii. Johnson & Johnson/Janssen**

9 407. McKinsey also working with Johnson & Johnson, whose role overseeing and
 10 contributing to the opioid crisis has been exhaustively detailed in other complaints. *See, e.g., City*
 11 *and County of San Francisco v. Purdue Pharma L.P.*, N.D. Cal. No. 18-2591, Doc. 128 (Mar. 13,
 12 2020). Johnson & Johnson occupied multiple roles within the opioids industry. Through its
 13 subsidiary, Janssen Pharmaceuticals (“Janssen”), it marketed and sold branded opioid products,
 14 including Duragesic (a transdermal fentanyl patch) and Nucynta (tramadol tablets and oral
 15 solution). Through its Noramco and Tasmanian Alkaloids subsidiaries, Johnson & Johnson farmed
 16 the poppy plant in New Zealand and created the precursor chemical and raw materials necessary to
 17 manufacture *all* opioids. Noramco and Tasmanian Alkaloids sold these raw materials to the other
 18 opioid manufacturers: Purdue, Endo, Mallinckrodt, and others. Johnson & Johnson was the origin
 19 point in the entire opioids supply chain.
 20

21 408. Just like McKinsey’s relationships with Purdue, Endo, and the others, McKinsey’s
 22 opioid-related work for Johnson & Johnson spanned decades.
 23

24 409. Just as Endo was led by former partner McKinsey partner Rajiv de Silva, Johnson
 25 & Johnson similarly relied on McKinsey as a pipeline for its own management timber. As described
 26 above, McKinsey alumni tend to move on to positions with McKinsey clients. Janssen’s current
 27

28 ²⁷² MCK-MDL2996-0358871, at 0358872; ENDO-OPIOID_MDL-02201117.

Director of Customer Marketing & Value Based Care was hired from McKinsey's PMP group. The relationship flows both ways: Janssen's former Vice President of Sales and Marketing for Janssen Pharmaceuticals is currently a McKinsey partner. Moreover, Ian Davis has been an independent director since 2010 and currently sits on the Audit and Regulatory Compliance committees of Johnson & Johnson's board. Previously, he was a Senior Partner at McKinsey, "having served as Chairman and Worldwide Managing Director from 2003 until 2009."²⁷³

410. Kevin Sneader, until recently McKinsey's global managing partner, and one of Davis' successors, described Davis as a "mentor" who was the managing partner of McKinsey's London office when Sneader was working there and "worked on one of his teams."²⁷⁴ Given Frazier's presence on the board, Johnson & Johnson was obviously an important account for McKinsey. At present, it is not known which McKinsey partner(s) was the Director(s) of Client Services for the Johnson & Johnson account.

411. What is known, however, is that McKinsey [REDACTED]

[REDACTED] On July 6, 2011, Ghatak attended an internal McKinsey call with the consultants working on the Johnson & Johnson account to discuss the "J&J Nucynta sales force disruption."²⁷⁶ The same day, Laura Moran, who like Ghatak worked both the Purdue and Endo accounts, also provided internal advice regarding Nucynta to her McKinsey partner Gerti Pellumbi, who was leading Nucynta sales efforts for the Johnson & Johnson account, and engagement manager Bryan Reinholt, who was with Pellumbi on

²⁷³ <https://www.jnj.com/leadership/ian-e-l-davis>

²⁷⁴ See Interview with Kevin Sneader, Harvard Project for Asian & International Relations, January 31, 2021, *available at* <https://www.youtube.com/watch?v=qed53EGG8kU>

²⁷⁵ JAN-NH-00167575.

²⁷⁶ MCK-MDL2996-0222833.

the Johnson & Johnson account.²⁷⁷ Martin Elling, one of the lead McKinsey partners on the Purdue account alongside Ghatak, attended internal McKinsey calls on March 25, 2010,²⁷⁸ and again on May 27, 2011 to discuss McKinsey’s work for Johnson & Johnson’s Nucynta.²⁷⁹ Then, on December 13, 2011, Elling attended a meeting with Johnson & Johnson personnel regarding “acceleration opportunities.”²⁸⁰ Aamir Malik attended the meeting with Elling, and, naturally, also worked on the Endo account.²⁸¹ Malik and Ghatak had an internal McKinsey meeting amongst themselves regarding the “Nucynta Kickoff” at Johnson & Johnson six months prior, on June 3, 2011.²⁸²

1. Noramco

412. Janssen was not the only Johnson & Johnson unit that [REDACTED] and Janssen was not Johnson & Johnson’s only division involved in the narcotics trade.

413. Opioids—all of them—are derivatives of opium, which is derived from the poppy plant. In order to sell opioids, someone needs to farm the opium poppy and process the harvest into the raw materials necessary for opioid manufacturers—all of them—to make their products.

414. Johnson & Johnson was that farmer. It owned Noramco and Tasmanian Alkaloids, which grew poppies in New Zealand and sold the raw ingredients for opioids to practically all manufacturers.

²⁷⁷ MCK-MDL2996-0419348.

²⁷⁸ MCK-MDL-2996-0256186.

²⁷⁹ MCK-MDL-2996-0255907.

²⁸⁰ MCK-MDL-2996-0255926.

²⁸¹ *Id.*; see also MCK-MDL-2996-0348536 (Example of Malik’s work on Endo account).

²⁸² MCK-MDL-2996-0261694.

1 415. On August 19, 2009, McKinsey's [REDACTED]

2 [REDACTED]
3 [REDACTED]²⁸³

4 416. [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]

9 417. Seven years later, in 2016, Johnson & Johnson exited the business by selling
10 Noramco and Tasmanian Alkaloids to SK Capital, a private equity firm focused on the
11 pharmaceuticals business, for approximately \$800 million.²⁸⁵ [REDACTED]
12 [REDACTED]
13 [REDACTED]

14 [REDACTED] Not only was McKinsey's advice
15 invaluable to Johnson & Johnson, the perspective McKinsey gained of the overall opioid market
16 from advising the principal upstream supplier to the entire industry would be invaluable in to its
17 own work with its other opioid manufacturer clients.

18 2. Duragesic

19 418. Fentanyl was first synthesized by Paul Janssen and his pharmaceutical company
20 Janssen Pharmaceuticals in 1959. In the 1990s, the company (by then owned by Johnson &
21 Johnson) developed Duragesic, which is a transdermal patch that administers fentanyl to the patient
22 wearing it.
23
24
25

26 ²⁸³ NORAMCO_TX_01136410.

27 ²⁸⁴ NORAMCO_TX_01136411, slide 4.

28 ²⁸⁵ Gareth Macdonald, "US Investor buys J&J's opiate API business and announces restructuring," *Outsourcing Pharma*, July 20, 2016, available at: <https://www.outsourcing-pharma.com/Article/2016/07/21/US-investor-buys-J-J-s-opiate-API-business-and-announces-restructuring>

1 419. “Duragesic proved to be one of the most successful analgesic pharmaceutical
2 products ever developed, with sales in 2004 (its last year of patent life) exceeding \$2.4 billion. The
3 success of the fentanyl patch caused many generic companies to produce equivalents once it went
4 off patent.”²⁸⁶

5 420. McKinsey was an integral part of fentanyl’s success. As early as 2002, McKinsey
6 was advising Johnson & Johnson regarding methods to boost sales of its opioids. For example, on
7 March 14, 2002, McKinsey prepared a confidential report for Johnson & Johnson’s subsidiary
8 Janssen regarding how to market their opioid Duragesic. Incredibly, one of the recommendations
9 McKinsey provided to Johnson & Johnson was that they concentrate their sales and marketing
10 efforts on doctors that were *already* prescribing large amounts of Purdue’s OxyContin.²⁸⁷

11 421. In other words, as early as 2002, McKinsey had such intricate knowledge of the
12 sales and marketing practices of opioid manufacturers, generally, and Purdue’s efforts with
13 OxyContin, specifically, that it was able to recommend to *a competitor of Purdue* that it boost its
14 own opioid sales by *following in the footsteps of Purdue*.

15 422. McKinsey also advised Johnson & Johnson to target Duragesic on “high abuse-risk
16 patients (e.g., males under 40).” This targeting would take advantage of the marketing claim that
17 Duragesic “was harder to abuse than other opioids on the market.”²⁸⁸

18 423. McKinsey helped Janssen target its opioid marketing by identifying “priority growth
19 opportunities” and growth strategies for Duragesic.²⁸⁹ In 2002, McKinsey considered “[w]hat are
20
21
22
23

24 ²⁸⁶ Theodore Stanley, “The Fentanyl Story,” The Journal of Pain, Vol. 15, No. 12 (December), 2014, pg. 1220, *available*
25 *at*: [https://www.jpain.org/article/S1526-5900\(14\)00905-5/pdf](https://www.jpain.org/article/S1526-5900(14)00905-5/pdf)

26 ²⁸⁷ Chris McGreal, *Johnson & Johnson faces multibillion opioids lawsuit that could upend big pharma*, The Guardian,
27 June 23, 2019, *available at*: [https://www.theguardian.com/us-news/2019/jun/22/johnson-and-johnson-opioids-crisis-](https://www.theguardian.com/us-news/2019/jun/22/johnson-and-johnson-opioids-crisis-lawsuit-latest-trial)
28 [lawsuit-latest-trial](https://www.theguardian.com/us-news/2019/jun/22/johnson-and-johnson-opioids-crisis-lawsuit-latest-trial)

²⁸⁸ Julia Lurie, “*Inside Johnson and Johnson’s Quiet Domination of the Opioid Market*,” June 11, 2019, Mother Jones,
27 *available at* [https://www.motherjones.com/politics/2019/06/johnson-and-johnson-opioid-poppies-tasmania-](https://www.motherjones.com/politics/2019/06/johnson-and-johnson-opioid-poppies-tasmania-oklahoma-lawsuit/)
28 [oklahoma-lawsuit/](https://www.motherjones.com/politics/2019/06/johnson-and-johnson-opioid-poppies-tasmania-oklahoma-lawsuit/)

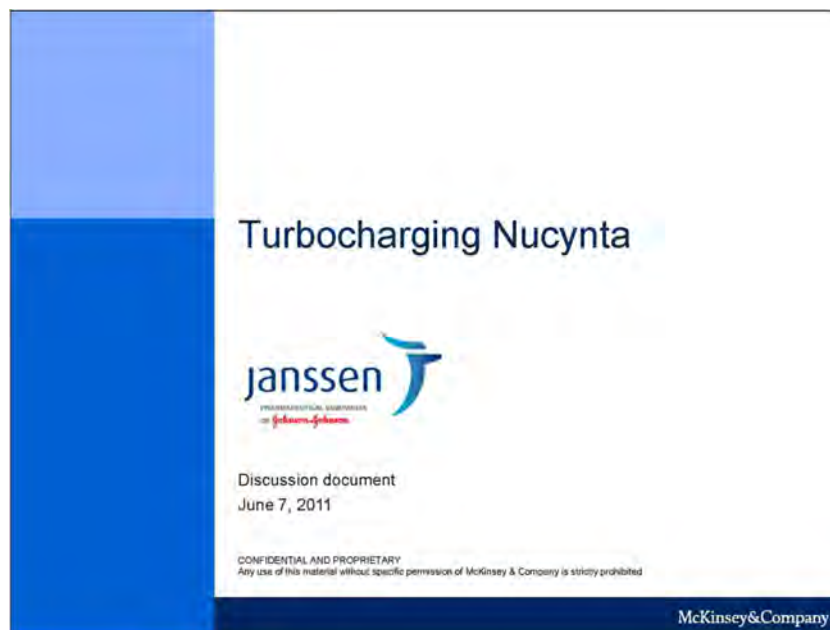
²⁸⁹ *Oklahoma v. Johnson & Johnson*, Oklahoma Proposed Findings & Conclusions, citing 5/30/19pm Tr. & S-1253;
see also JAN-MS-00481545 (Deem-Eshleman Ex 73).

settings of care for opioid high-prescribers and treaters of back pain,” listing the “elderly” as an example;²⁹⁰

²⁹¹

3. Turbocharging Nucynta

424. McKinsey’s infamous Project Turbocharge to boost OxyContin sales at Purdue in 2013 and 2014—the same project detailed in Purdue’s 2020 guilty plea with the Department of Justice—was not McKinsey’s first experience turbocharging opioid sales. Before OxyContin, there was Nucynta.²⁹²



425. Nucynta was Janssen’s branded tapentadol product. Tapentadol is generally regarded as a moderately strong opioid. Nucynta was first approved as a Schedule II controlled opioid agonist tablet and oral solution in 2008 and indicated for “relief of moderate to severe acute pain in patients 18 years of age or older.” In 2011, Janssen obtained approval for a long-acting

²⁹⁰ *Oklahoma v. Johnson & Johnson*, 5/30/19 Tr. At 46:1-15.

²⁹¹ JAN-MS-00481547 (Deem-Eshleman Ex 74) .

²⁹² MCK-MDL-2996-0135636.

1 version Nucynta ER, which was indicated for “management of moderate to severe chronic pain in
2 adults and neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults.”

3 426. McKinsey is a repeat opioid sales turbocharger. McKinsey’s efforts to turbocharge
4 Nucynta sales resembled those it later deployed in more robust form at Purdue a few years later.
5 For example, “physician prescribing habits,” and “switching behavior,” were external factors
6 McKinsey identified as key issues “impacting future Nucynta growth.” Understanding these issues
7 at a granular level would be crucial, including “What is physician/market awareness of Nucynta
8 ER? By physician segment?”²⁹³ These same factors drove McKinsey’s later work turbocharging
9 OxyContin.
10

11 427. Along the way, [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]

16 428. Despite this ambivalence about tamper-resistance, in a status update on June 23,
17 2011, McKinsey informed Janssen that its “initial physician interview findings” indicate Nucynta
18 ER has “lower addictive/abuse potential and side-effect profile as key differentiators vs. Oxycontin
19 ER.”²⁹⁵
20

21 429. As part of the turbocharge process, [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25
26
27

28 ²⁹³ MCK-MDL-2996-0135636.

²⁹⁴ JAN-MS-00322271.

²⁹⁵ MCK-MDL-2996-0009526, at 0009529.

1 [REDACTED]
 2 [REDACTED]²⁹⁶
 3 430. By 2014, Janssen was began exploring the sale of Nucynta, and McKinsey was
 4 involved in the process. Incredibly [REDACTED]
 5 [REDACTED]²⁹⁷ Purdue ultimately did not purchase Nucynta. Instead, in 2015, Johnson & Johnson's
 6 Janssen unit sold its Nucynta rights to another manufacturer, Depomed Inc., for just over one billion
 7 dollars.²⁹⁸

9 431. The year prior, Nucynta accounted for \$172 million in annual sales for Janssen.
 10 Janssen described the Nucynta sale to Depomed as "a strategic decision designed to focus efforts
 11 on growth efforts."²⁹⁹ Depomed, for its part, saw the Nucynta acquisition as a transformational
 12 opportunity to position itself as "a pain and neurology-focused specialty pharmaceutical
 13 company."³⁰⁰

15 432. When Depomed bought Nucynta, [REDACTED]
 16 [REDACTED]
 17 [REDACTED]
 18 [REDACTED]
 19 [REDACTED]
 20 [REDACTED]
 21 [REDACTED]³⁰¹

22 ²⁹⁶ JAN-MS-02272779.

23 ²⁹⁷ PPLPC02300066101 [REDACTED]
 24 [REDACTED]
 25 [REDACTED]

26 ²⁹⁸ See <https://www.prnewswire.com/news-releases/depomed-announces-closing-of-acquisition-of-us-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-from-janssen-pharmaceuticals-inc-for-105-billion-300060453.html>

27 ²⁹⁹ Josh Beckerman, "DepoMed to Buy U.S. Rights to Nucynta From J&J Unit," *Wall Street Journal*, January 16, 2015, available at: <https://www.wsj.com/articles/depomed-to-buy-u-s-rights-to-nucynta-from-j-j-unit-1421357503>

28 ³⁰⁰ *Id.*

³⁰¹ DEPO-CDI-00071072 (emphasis added).

1 **iii. Other Manufacturers**

2 433. McKinsey worked with numerous other manufacturers to promote the sale of
3 opioids. To date, Plaintiffs have identified as McKinsey clients [REDACTED]⁰² and [REDACTED]

4 [REDACTED]³⁰³

5
6 434. Coordination among these industry participants was a natural outgrowth of the fact
7 that McKinsey had existing client relationships with each participant. For instance, on May 7, 2009,
8 Richard Sackler's personal counselor, McKinsey partner Maria Gordian, [REDACTED]

9 [REDACTED]
10 [REDACTED]³⁰⁴

11 435. [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 436. [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

26 _____
27 ³⁰² MNK-MDL_001756041; MNK-T1_0000968026; MN-T1_0004715842; MNK-T1_0005985720.

28 ³⁰³ TEVA_CHI_00187019.

³⁰⁴ TEVA_CHI_00187019.

³⁰⁵ TEVA_CHI_00187023.

³⁰⁶ See ALLERGAN_MDL_00637407. [REDACTED]

iv. **McKinsey's Work with Opioid Distributors**

437. McKinsey worked with opioid distributor AmerisourceBergen [REDACTED]

[REDACTED]³⁰⁷

438. McKinsey worked with opioid distributor McKesson on the company's [REDACTED]

v. **McKinsey's Work with the FDA**

439. As described above, McKinsey assisted Purdue and others to confront FDA regulations that posed threats to their clients' ability to maximize revenues from their opioid products. McKinsey's role in shepherding its clients through regulatory interactions takes on a different hue when considered in light of one of McKinsey's other clients: the Food and Drug Administration itself.

440. Indeed, the FDA has proved a massive client for McKinsey, who since 2000 has endeavored to expand its public sector practice under the direction and leadership of Nancy Killefer, a now-retired senior partner and director of the firm.³⁰⁹ Since 2008, the FDA has paid McKinsey more than \$140 million.³¹⁰ A significant portion of that work for the FDA related to the FDA's Center for Drug Evaluation and Research ("CDER"). The CDER is the principal division tasked with approving, among other classes of drugs, opioids. Since 2008, McKinsey has been awarded at least 17 contracts worth at least \$48 million for CDER work.³¹¹

441. The REMS protocols, discussed above, that McKinsey assisted Purdue and others in surmounting beginning in 2008 and culminating in 2012, were overseen by CDER.³¹²

³⁰⁷ ABDCMDL12135609, slide 5.

³⁰⁸ MCKSTCT00753097; MCKSTCT00753098.

³⁰⁹ Duff McDonald, *The Firm*. Killefer is also a director of Cardinal Health, one of the distributor defendants in the ongoing nationwide opioid litigation, and a company subject to FDA regulations.

³¹⁰ Letter to Dr. Janet Woodcock from Senator Margaret Hassan et al, August 23, 2021, *available at*: https://www.hassan.senate.gov/imo/media/doc/fda-mckinsey_letter-final-210823.pdf ("Hassan Letter")

³¹¹ *Id.*

³¹² *Id.*

1 442. Meanwhile, in 2010, McKinsey advised the FDA on building a monitoring system
2 called “track and trace” to assist in the identification of potentially improper distribution of harmful
3 prescription drugs, such as opioids. “The ‘track and trace’ system deeply impacted McKinsey
4 clients, including the nation’s three largest drug distributors—McKesson, AmerisourceBergen, and
5 Cardinal Health [where Killefer has been a director since 2015].”³¹³

6
7 443. Under one contract, McKinsey developed a roadmap and implemented plans to
8 modernize CDER’s new drug regulatory program. Under another, McKinsey developed a
9 framework to increase information technology project delivery across CDER.³¹⁴

10 444. In 2007, Congress passed the Food and Drug Administration Amendments Act
11 (“FDAAA”), which placed new restrictions on the use of certain high risk prescription drugs,
12 including opioids. The new law mandated that FDA require manufacturers of certain drugs to create
13 REMS.
14

15 445. The FDAAA also required the Secretary of Health and Human Services “to develop
16 standards and identify and validate effective technologies for the purpose of securing the drug
17 supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or
18 expired drugs.” 21 U.S.C. § 355e(a).

19 446. In 2010 and 2011, under the FDAAA, the FDA awarded McKinsey contracts to
20 design a “track and trace” system to monitor prescription drugs, including opioids, throughout the
21 supply chain and to streamline the drug approval process. The track and trace system had the
22 greatest effect on drug distributors, including McKinsey clients McKesson, AmerisourceBergen,
23 and Cardinal Health.³¹⁵
24

25
26
27 ³¹³ See <http://cg.cardinalhealth.com/board-of-directors/default.aspx>; Hassan Letter.

28 ³¹⁴ Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, *available at*:
https://www.grassley.senate.gov/imo/media/doc/fda_to_grassley_-_mckinsey_conflicts_of_interest.pdf

³¹⁵ Hassan Letter.

1 447. Under these contracts, McKinsey was required to consult with “supply chain
2 stakeholders,” which likely included these three McKinsey clients as well as pharmaceutical
3 manufacturers.³¹⁶

4 448. In 2011, McKinsey also won a \$1.8 million contract with CDER’s Office of
5 Surveillance and Epidemiology (“OSE”), which monitors and evaluates the safety profiles of drugs
6 available to American consumers.³¹⁷ OSE “evaluates more than 2 million adverse event reports
7 submitted every year to FDA’s MedWatch program” and provides “risk management expertise on
8 development and implementation of programs and initiatives to support [CDER’s] policies related
9 to [REMS] authorities.”³¹⁸

10 449. The OSE contract tasked McKinsey with a widespread mission of understanding
11 how OSE functions within the context of a broader system of drug safety in CDER and ultimately
12 developing and implementing a new operating model. In other words, McKinsey helped to
13 restructure a key body that has oversight over the opioid supply chain.

14 450. The 2012 Food and Drug Administration Safety and Innovation Act required the
15 FDA to modernize Sentinel, a system meant to monitor the safety of drugs once they are on the
16 market.³¹⁹ According to the FDA, “Sentinel generates *real-world evidence* to support regulatory
17 actions aimed at protecting the public’s health,” which in turn “inform[s] healthcare provider
18 decision-making for patients.”³²⁰

19 451. A 2014 contract with the FDA charged McKinsey with assessing the “strengths,
20 limitations and appropriate use” of Sentinel. Like the track and trace contract, the Sentinel project
21

22
23
24
25 _____
26 ³¹⁶ *Id.*

27 ³¹⁷ <https://www.documentcloud.org/documents/21071060-mckinsey-ose-contract>

28 ³¹⁸ <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-office-surveillance-and-epidemiology>

³¹⁹ https://www.documentcloud.org/documents/21071047-r_sentinel_assessment_award_contract_sow-redacted-pr

³²⁰ <https://www.fda.gov/files/about%20fda/published/Sentinel-System-Overview—Presentation.pdf>;
<https://www.healthaffairs.org/doi/10.1377/hpb20150604.936915/full/>

1 required McKinsey to interview “external stakeholders,” including “industry organizations” and
 2 “drug and device industry leaders.”³²¹ McKinsey also evaluated how the FDA employees used
 3 Sentinel to inform regulatory decision making.³²²

4 452. McKinsey performed similar work for the FDA as recently as 2019,³²³ when it
 5 signed a contract extension with the agency for work relating to the FDA’s efforts to modernize the
 6 process by which it regulates new drugs.³²⁴

7 453. The FDA’s drug tracking programs have been panned as failures.³²⁵

8 454. A theme was emerging: as new legislation and regulatory systems were enacted that
 9 could have hampered the opioid supply chain, McKinsey stepped in as a key consultant for the
 10 FDA. Each time, the new system failed to reign in the out-of-control opioid market. While the FDA
 11 was not solely responsible for regulating the opioid industry and McKinsey was not wholly
 12 responsible for the FDA’s inaction, tools like Sentinel and track and trace could have been
 13 implemented in a way to provide new information to combat the country’s growing opioid crisis.

14 455. At the same time it was consulting for the FDA, McKinsey was working with its
 15 opioid industry clients on how skirt the FDA’s regulatory systems.

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 19
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 21

 22 ³²¹ Ian MacDougall, “McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the
 Agency,” *ProPublica* (Oct. 4, 2021), *available at* [https://www.propublica.org/article/mckinsey-never-told-the-fda-it-](https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency)
 was-working-for-opioid-makers-while-also-working-for-the-agency

23 ³²² Letter to Bob Sternfels from Representative Carolyn B. Maloney, Nov. 5, 2021, *available at*:
 24 [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf)
 McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf

25 ³²³ Ian MacDougall, “McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the
 Agency,” *ProPublica* (Oct. 4, 2021), *available at* [https://www.propublica.org/article/mckinsey-never-told-the-fda-it-](https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency)
 was-working-for-opioid-makers-while-also-working-for-the-agency

26 ³²⁴ Letter to Bob Sternfels from Representative Carolyn B. Maloney, Nov. 5, 2021, *available at*:
 27 [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-11-05.CBM%20to%20Sternfels-McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf)
 McKinsey%20re%20Document%20and%20Information%20Request%20%28001%29.pdf

28 ³²⁵ Sabrina Tavernise, “F.D.A. Faulted for Problems With Drug Tracking” *The New York Times*, Jan. 14, 2016,
available at <https://www.nytimes.com/2016/01/15/health/fda-faulted-for-problems-with-drug-tracking.html>;
<https://www.gao.gov/assets/gao-16-192.pdf>

1 456. For example, McKinsey advised Purdue on how to soften the FDA’s proposed
2 REMS and on coordinating with other opioid manufacturers to advocate against strict oversight.³²⁶
3 The finalized REMS for opioid products was largely devoid of the restrictions that FDA had
4 initially proposed.³²⁷

5 457. McKinsey’s work with the FDA was a key factor in why pharmaceutical industry
6 clients tapped McKinsey for FDA-related work. For example, in endorsing McKinsey’s proposed
7 strategy of banding together with other opioid manufacturers, Purdue CEO John Stewart suggested
8 that the consultant itself facilitate the pharmaceutical group’s approach to FDA. He wrote: “Perhaps
9 a consultant such as McKinsey who did similar work in the industry and FDA on some aspects of
10 clinical trials or a healthcare-related group that would be interested in playing an active role in the
11 program’s development and delivery would be a good choice.”³²⁸

12 458. McKinsey performed work for the FDA without disclosing its potential conflicts of
13 interest to the FDA in violation of the contracts between the company and the agency.

14 459. The FDA typically includes conflict of interest clauses in its contracts and relies on
15 contractors to assess and report any conflicts. McKinsey’s contracts with the FDA related to CDER
16 processes contained such provisions. One contract required McKinsey to “make an immediate and
17 full disclosure, in writing, . . . of any potential or actual organizational conflict of interest or the
18 existence of any facts that may cause a reasonably prudent person to question the contractor’s
19 impartiality because of the appearance or existence of bias.”³²⁹
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26 ³²⁶ Hassan Letter.

27 ³²⁷ Hassan Letter; Maloney Letter.

28 ³²⁸ Purdue Bankruptcy, Doc. 2166-5, at 58-59.

³²⁹ Ian MacDougall, McKinsey Never Told the FDA It Was Working for Opioid Makers While Also Working for the Agency, *ProPublica* (Oct. 4, 2021), available at <https://www.propublica.org/article/mckinsey-never-told-the-fda-it-was-working-for-opioid-makers-while-also-working-for-the-agency>

1 460. But McKinsey never disclosed its work on behalf of opioid supply clients to the
2 FDA despite having a hand in developing some of the FDA's most important regulatory
3 processes.³³⁰

4 461. Disclosing its conflicts might have turned off the lucrative tap to not only FDA
5 contracts but also to pharmaceutical industry clients, given the clear value such clients placed on
6 McKinsey's work for the FDA.

7 462. McKinsey's manipulation of regulatory requirements—whether to skirt its own
8 contractual requirements or to bend processes that regulate its clients—is nothing new. McKinsey
9 has come under fire from the Office of Inspector General for the General Services Administration
10 for contract procurement violations³³¹ and from the Justice Department related to violation of
11 Chapter 11 bankruptcy rules.³³² Most recently, six senators have begun to investigate the
12 relationship between McKinsey and the FDA³³³ the House Committee on Oversight and Reform is
13 exploring its abusive conduct in connection with the opioid industry.³³⁴

14 463. As one commentator noted, McKinsey's conduct suggests that it “behaves as if it
15 believes the rules should bend to its way of doing things, not the other way around.”³³⁵

16
17
18 **f. McKinsey's Efforts to Increase the Overall Size of the Opioid Market: the**
19 **Larger the Pie, the Larger the Slice**

20 464. McKinsey advised multiple opioid manufacturers regarding how to grow opioid
21 sales. In order to benefit all its clients, McKinsey engaged in efforts to grow the entire opioid
22

23
24 ³³⁰ *Id.*; Letter to Senator Chuck Grassley from Andrew Tantillo, Oct. 22, 2021, *available at*
https://www.grassley.senate.gov/imo/media/doc/fda_to_grassley_-_mckinsey_conflicts_of_interest.pdf

25 ³³¹ Ian MacDougall, How McKinsey Makes Its Own Rules, *ProPublica* (Dec. 14, 2019), *available at*
<https://www.propublica.org/article/how-mckinsey-makes-its-own-rules>

26 ³³² Mary Williams Walsh and Emily Flitter, McKinsey Faces Criminal Inquiry Over Bankruptcy Case Conduct, *New*
York Times, Nov. 8, 2019, *available at* [https://www.nytimes.com/2019/11/08/business/mckinsey-criminal-](https://www.nytimes.com/2019/11/08/business/mckinsey-criminal-investigation-bankruptcy.html)
27 [investigation-bankruptcy.html](https://www.nytimes.com/2019/11/08/business/mckinsey-criminal-investigation-bankruptcy.html)

28 ³³³ Hassan Letter.

³³⁴ Maloney Letter.

³³⁵ Ian MacDougall, How McKinsey Makes Its Own Rules, *ProPublica* (Dec. 14, 2019), *available at*
<https://www.propublica.org/article/how-mckinsey-makes-its-own-rules>

1 market, and not only each individual client's share of it. The theory, basically, is that a rising tide
2 lifts all boats.

3 465. For example, Purdue incentivized its sales staff "to increase not just sales of
4 OxyContin but also generic versions of extended release oxycodone." Typically, one would not
5 wish to encourage the sales of generic competitors that offer a similar product to one's own. If,
6 however, the goal is to position a company so as to look like an attractive acquisition target, the
7 growth of the overall opioid market is just as important as one's own market share: "Whereas
8 pharma salespeople are usually compensated based on their ability to grow sales of a particular
9 medicine, part of the bonus for Purdue's staff was calculated in relation to the size of the overall
10 market."³³⁶ McKinsey designed that plan.³³⁷

12 466. This notion that the size of a company's market share is not as important as the size
13 of the *overall* market in which it competes is a core insight of McKinsey's granular approach to
14 identifying corporate growth opportunities. Describing their authors' conclusions in *The*
15 *Granularity of Growth*, McKinsey stated, "One of their most surprising conclusions is that
16 increased market-share is seldom a driver of growth. They contend, instead, that growth is driven
17
18
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20

21 ³³⁶ See David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times, September 9,
2018, available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

22 ³³⁷ Worth noting is that this strategy of increasing overall opioid sales directly benefitted the Sacklers through their
23 ownership of Rhodes Pharma, a generic opioid manufacturer. Naturally, McKinsey worked with the Sacklers in
24 connection with Rhodes as well, including proposing ideas for synergizing Purdue and Rhodes. See, e.g., MCK-
25 MDL2996-0324955; MCK-MDL2996-0285201. Especially worth noting is that this strategy also benefitted
26 McKinsey's other opioid clients as well. As one observer wrote: "They have a huge amount of inside information,
which raises serious conflict issues at multiple levels," stated a former consultant, referring to McKinsey's influential
27 role as advisor to multiple participants in a given industry, such as opioid manufacturing. It "puts them in a kind of
oligarchic position." Michelle Celarier, *The Story McKinsey Didn't Want Written*, Institutional Investor, July 8, 2019,
28 available at: <https://www.institutionalinvestor.com/article/b1g5zjdc97k2y/The-Story-McKinsey-Didn-t-Want-Written>.

For example, in an August 15, 2013 presentation to Purdue management entitled "Identifying OxyContin
Growth Opportunities," McKinsey noted that "McKinsey's knowledge of the ways other pharma companies operate
suggests Purdue should reassess the roles of MSL and HECON Groups – and further drive the salesforce to be more
responsive to formulary coverage changes." (emphasis added).

by where a company chooses to compete: which market segments it participates in . . . the key is to focus on granularity, to breakdown big-picture strategy into its smallest relevant components.”³³⁸

467. In other words, “Purdue’s marketing force was indirectly supporting sales of millions of pills marketed by rival companies.”³³⁹ “It’s the equivalent of asking a McDonald’s store manager to grow sales of Burger King and KFC,” stated a government official with the Department of Health and Human Services.³⁴⁰

f. McKinsey Portrays Itself as Part of a Solution to a Problem It was Integral in Creating.

468. McKinsey’s work on the other side of the aisle—helping clients address opioid abuse and addiction—further proves that it was well aware of the risks of OxyContin, and thus the risks of pushing OxyContin sales and high dose sales, and targeting the highest-volume prescribers. McKinsey advised Purdue on “Project Tango,” a 2014 plan to enter the addiction drug market.³⁴¹

McKinsey noted the [REDACTED]

469. More than assisting specific clients with addressing the crisis itself, McKinsey saw the ongoing opioid crisis as an opportunity to posture itself as contributing more broadly to *society*. McKinsey likes to think of itself as a change agent capable of solving problems that truly matter, and the opioid crisis is one McKinsey realizes matters. Dr. Sarun Charumilind, a McKinsey partner in Philadelphia, “has led the firm’s support to clients and *society* to combat the opioid crisis.”³⁴³

³³⁸ *The granularity of growth*, Book Excerpt, McKinsey & Company, March 1, 2008, available at: <https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-granularity-of-growth>

³³⁹ See David Crow, *How Purdue’s ‘one-two’ punch fueled the market for opioids*, Financial Times, September 9, 2018, available at: <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>

³⁴⁰ *Id.*

³⁴¹ See David Armstrong, *OxyContin Maker Explored Expansion Into “Attractive” Anti-Addiction Market*, ProPublica (Jan. 30, 2019), available at <https://www.propublica.org/article/oxycontin-purdue-pharma-massachusetts-lawsuit-anti-addiction-market>.

³⁴² PPLPC023000714734.

³⁴³ See <https://www.mckinsey.com/our-people/sarun-charumilind>

1 470. In Detroit, partner Razili Lewis also helps “clients and *society* combat the opioids
2 crisis.” She does so by providing “insights, expertise, analytics, and technology.”³⁴⁴

3 471. Over in Cleveland, senior partner Tom Latkovic also “helps clients and *society*
4 combat the opioids crisis.”³⁴⁵

5 472. Kana Enomoto, a senior expert in Washington, D.C., is a “national leader in mental
6 health and substance-use policy,” who acted as a “content director” on a study to “raise awareness
7 about opioid-use disorders.” She also provided strategic guidance to the United States Surgeon
8 General regarding efforts to “combat the opioid epidemic” when she was his Chief of Staff.³⁴⁶

9 473. McKinsey consistently states that it takes its obligations to society seriously. Indeed,
10 the firm has established a center.³⁴⁷

11
12 The Center for Societal Benefit through Healthcare was established to build on the
13 long-standing mission of McKinsey’s Public & Social Sector and Healthcare
14 Systems & Services Practices to improve healthcare. The Center’s work is funded
15 solely by McKinsey; it is not commissioned by any business, government, or other
16 institution. The Center brings a range of capabilities to bear, including McKinsey’s
17 healthcare expertise, advanced analytics, functional knowledge, technology assets,
18 network, and investment capacity.

19 The Center aspires to collaborate with other organizations to drive positive
20 innovation to improve overall health and well-being and reduce healthcare
21 disparities.

22 474. The Center has focused on addressing the impacts of the opioid crisis on society.
23 One of the metrics that McKinsey uses to track the opioid crisis *as a matter of public health* is the
24 “opioid prescribing rate” per 100 people in every county in the United States.³⁴⁸

25 475. As McKinsey’s data visualization makes clear, there is an association between areas
26 with higher opioid prescribing rates and higher instances of opioid use disorder.

27 ³⁴⁴ See <https://www.mckinsey.com/our-people/razili-lewis>

28 ³⁴⁵ See <https://www.mckinsey.com/our-people/tom-latkovic>

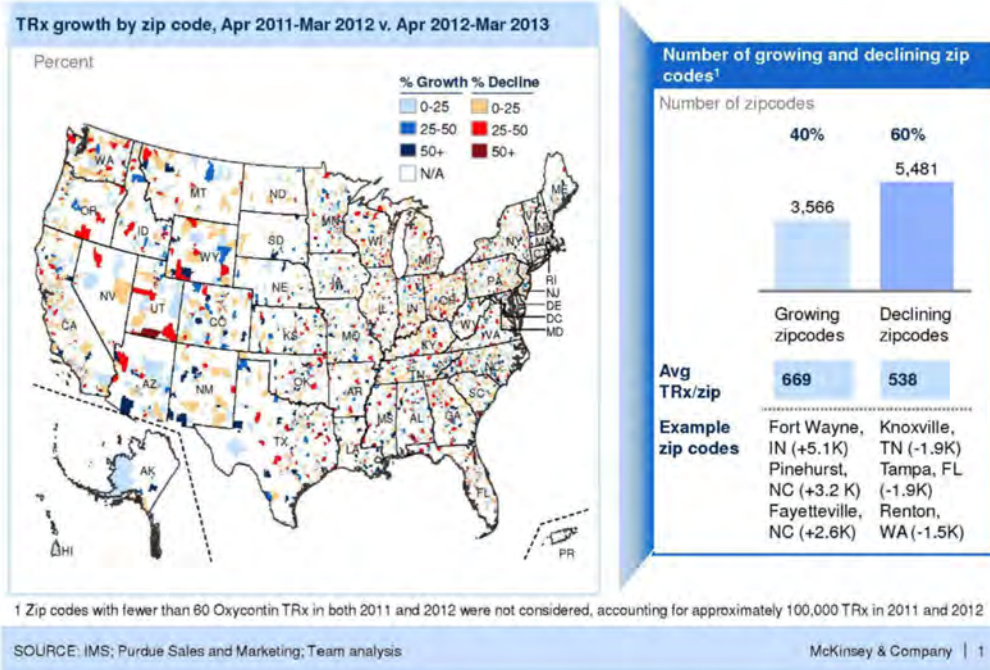
³⁴⁶ See <https://www.mckinsey.com/our-people/kana-enomoto>

³⁴⁷ See <https://www.mckinsey.com/industries/healthcare-systems-and-services/how-we-help-clients/center-for-societal-benefit-through-healthcare/overview>

³⁴⁸ See https://csbh-dashboard.mckinsey.com/#/data-insights?chart=SC&geo=County&lob=All&metric1=opioid_rxrate&metric2=oud&tab=Map

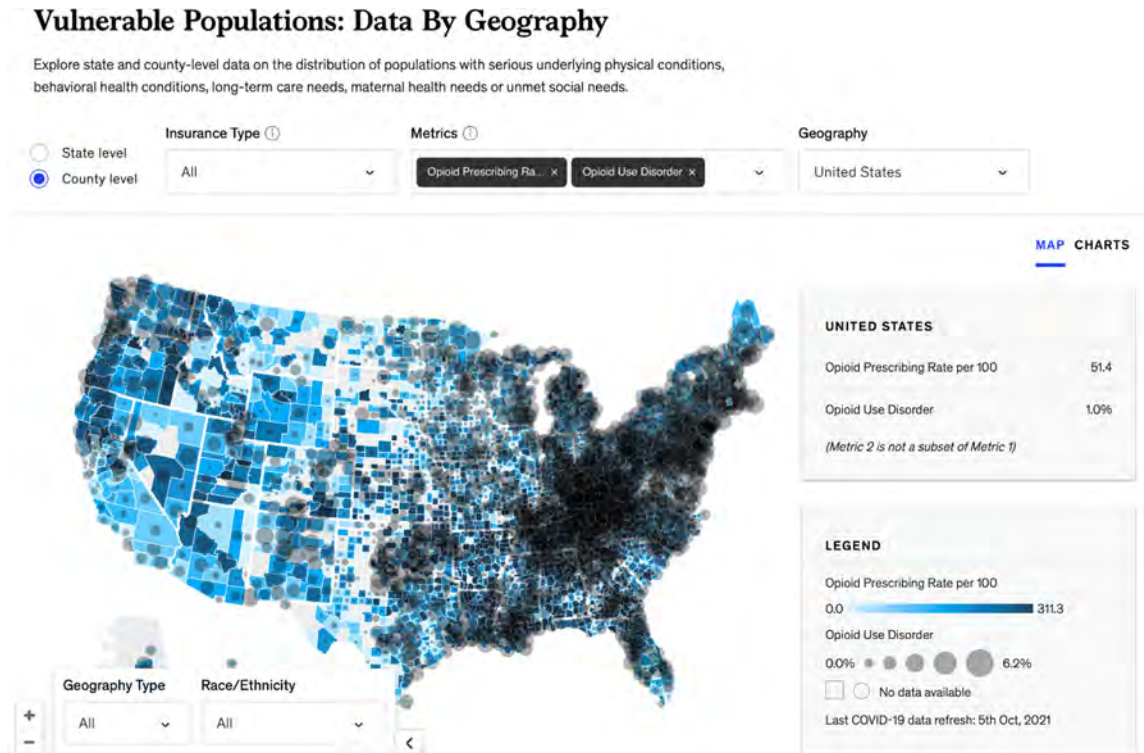
476. The Center's data visualization is also reminiscent of similar work McKinsey did for Purdue in 2013, although the analysis McKinsey did for Purdue was more granular, analyzing opioid prescribing patterns on the *zip-code* level in all 50 states, as opposed to the county level:³⁴⁹

Exhibit 1: OxyContin growth by geography



³⁴⁹ MCK-MAAG-0024283.

477. In other words, the “opioid prescribing rate” was a metric McKinsey worked with its client to boost for years. Now McKinsey measures the extent of the crisis by the same metric:



478. Meanwhile, McKinsey has partnered with Shatterproof, a national non-profit organization dedicated to reversing the addiction crisis in the United States, to prepare a report on overcoming stigma associated with opioid use disorder.³⁵⁰ McKinsey touts the Shatterproof partnership on its webpage as an example of “our societal impact.”³⁵¹

479. In August 2017, McKinsey prepared a presentation entitled “Perspectives on Combatting the Opioid Crisis,” which referenced its work on combatting opioid addiction for various other entities:

³⁵⁰ See <https://www.shatterproof.org/sites/default/files/2020-07/A-Movement-to-End-Addiction-Stigma.pdf>

³⁵¹ See <https://www.mckinsey.com/us/our-societal-impact>

RECENT CLIENT EXPERIENCE

- » Designed and helped launch a health home program to expand resources and accountability for **substance abuse treatment**
- » Conducted a **state wide assessment of opioid prescriber performance** in terms of prescribing rate, dosage, and duration
- » Defined clinically relevant opioid quality measures for a **portfolio of episodes-of-care**
- » Defined clinically relevant opioid quality measures for a **Patient Centered Medical Home and Accountable Care Organizations**
- » Used predictive analytics to develop multi-faceted approach to **assess patient risk** for opioid addiction
- » Used geo-spatial and social network analytics to **assess intensity of opioid abuse and treatment needs**
- » Integrated claims and PDMP data to **generate transparency on provider prescribing practices**
- » Developed a **substance abuse episode of care** focused on priority patient journeys

480. In June 2018, Dr. Charumilind and Mr. Latkovic, along with fellow McKinsey partner Elena Mendez-Escobar, published a public report, “Ten insights on the Opioid crisis from claims data analysis,” stating information about the risks of opioids that McKinsey knew while advising Purdue to sell more opioids and higher dose opioids, and target the highest volume prescribers:

- a. “Providers frequently prescribe opioids to patients with known or potential risk factors for abuse[;]”
- b. “Approximately 35% of the patients given opioid prescriptions in our analysis had features that put them at increased risk for opioid abuse[;]”
- c. “Most opioids are prescribed by providers other than the natural ‘quarterback’ of a patient’s underlying complaint or condition. . . . This finding makes clear that high-dose prescribers and multi-prescriber patterns are separate issues—and both are important to address[;]” and

d. “A small portion of opioid use originates in emergency departments.”³⁵²

481. Two months later, the same authors, joined by Ms. Lewis, published “Why we need bolder action to combat the opioid epidemic.”³⁵³ “Our research suggests that much broader – and bolder – action is required,” they announced.³⁵⁴

h. Coda

482. Marvin Bower, the McKinsey legend who admonished, “Deliver bad news if you must, but deliver it properly,” died in 2003, one year before the firm began working with Purdue.

483. McKinsey’s work with Purdue would have been unrecognizable to Bower, one of the founders of modern management consulting. Instead of acknowledging the elephant in the room—that Purdue’s business was knowingly maximizing the amount of addictive and deadly opioids sold in the United States—and delivering that bad news promptly properly to the client, McKinsey instead committed to partner with Purdue to maximize opioid sales without regard to the consequences.

484. On October 23, 2017, the president of the United States declared the ongoing nationwide opioid epidemic a “public health emergency.” Even at this late hour in the crisis, McKinsey continued to propose solutions to the Sacklers and Purdue to further boost opioid sales. These solutions were fashioned, in perfect McKinsey parlance, as “high impact interventions to rapidly address market access challenges.”

485. Less than two months after the public health emergency declaration, McKinsey proposed these high impact interventions to Purdue and its board. Among them was perhaps

³⁵² <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/ten-insights-on-the-us-opioid-crisis-from-claims-data-analysis>

³⁵³ See <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic>

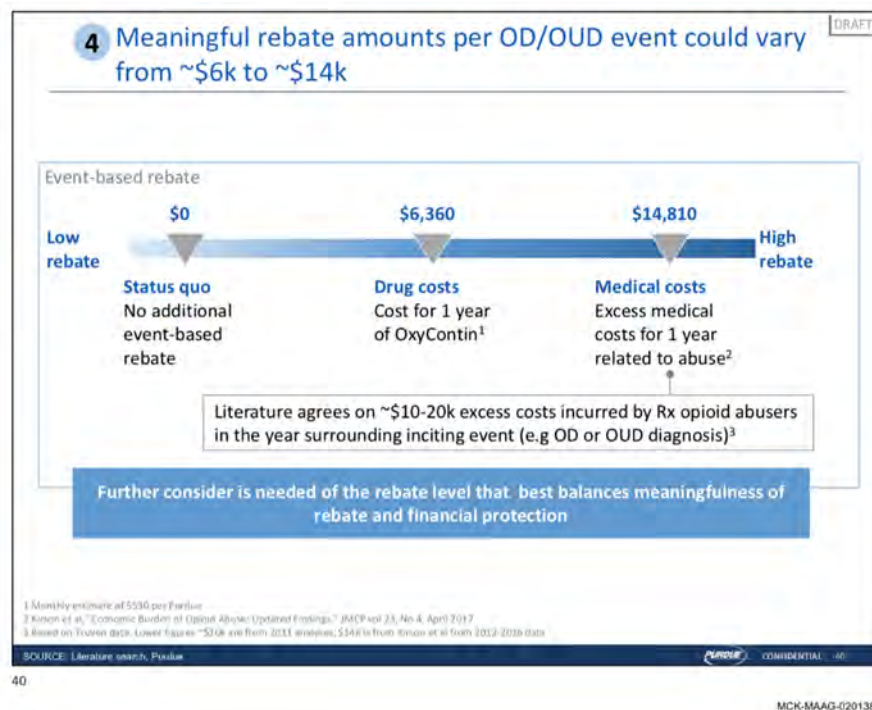
³⁵⁴ *Id.*

McKinsey's most audacious gambit of the entire Purdue relationship: paying money— "rebates"— to health insurers whenever someone overdosed on Purdue's drug.

486. These payments for future OxyContin overdoses were christened "Event-Based contracts."³⁵⁵

487. Helpfully, McKinsey provided estimates for the future costs of these "events."³⁵⁶ McKinsey noted that, if Purdue were to start making overdose payments, it would "need to determine which payment amount is optimal."

488. A "meaningful" amount, according to McKinsey, would be somewhere between six and fifteen thousand dollars for each person who overdoses or develops opioid-use disorder as a result of Purdue's drugs:



³⁵⁵ "Consultant-ese," when applied to work as grim as maximizing opioid sales in the face of a national disaster, led one former McKinsey consultant to state: "This is the banality of evil, M.B.A. edition." Walt Bogdanich and Michael Forsythe, *McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin Overdoses*, New York Times, November 27, 2020, available at: <https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontin-opioids.html>

³⁵⁶ McKinsey defined an "event" as "first occurrence for overdose or opioid use disorder."

489. The money would be paid to health insurers for the increased costs of additional medical services that resulted from the fact that Purdue's medications caused opioid-use disorder and overdoses in people whose health care costs were the payors' obligation. The money McKinsey proposed Purdue pay out in these circumstances would not go to the individuals afflicted, nor the estates of the dead.

490. McKinsey's analysis also suggested that it could predict the number of people who would become addicted to opioids or overdose on pills sold through Purdue's downstream customers. McKinsey "projected that in 2019, for example, 2,484 CVS customers would either have an overdose or develop an opioid use disorder."³⁵⁷

491. It is little surprise, then, that McKinsey was concerned with its legal liability for this work. Within months of recommending "event-based contracts" to Purdue, Martin Elling raised this concern with Arnab Ghatak and suggested corrective action: destroying evidence.

Message

From: Martin Elling [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6B33C3264F744B04AF05FA59341271BE-MARTIN ELLI]
Sent: 7/4/2018 12:10:13 PM
To: A G [drarnabghatak@gmail.com]
Subject: Re: [EXT]Re: Howdy

Have a great fourth. M

> On Jul 4, 2018, at 2:01 PM, A G <drarnabghatak@gmail.com> wrote:

>
 > Thanks for the heads up. Will do.

>
 >> On Jul 4, 2018, at 7:57 AM, Martin Elling <martin_elling@mckinsey.com> wrote:

>>
 >> Just saw in the FT that Judy Lewent is being sued by states attorneys general for her role on the Purdue Board. It probably makes sense to have a quick conversation with the risk committee to see if we should be doing anything other than eliminating all our documents and emails. Suspect not but as things get tougher there someone might turn to us. M

>>
 >> +=====+
 >> This email is confidential and may be privileged. If you have received it
 >> in error, please notify us immediately and then delete it. Please do not
 >> copy it, disclose its contents or use it for any purpose.
 >> +=====+

³⁵⁷ Walt Bogdanich and Michael Forsythe, *McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin Overdoses*, N.Y. Times (Nov. 27, 2020, updated Dec. 17, 2020), <https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontin-opioids.html>

1 492. Elling’s prediction that things would “get tougher” for Purdue would prove
2 prescient.

3 **i. Guilty Again - 2020**

4 493. On October 20, 2020, Purdue—McKinsey’s co-conspirator—agreed with the
5 United States Department of Justice to plead guilty to improper marketing of OxyContin and other
6 opioids again (the “2020 Settlement Agreement”). This time the plea agreement concerned conduct
7 from 2010 to 2018. The agreement includes \$8.3 billion in penalties from Purdue and \$225 million
8 from the Sackler family.
9

10 494. Purdue pleaded guilty to a dual-object conspiracy to defraud the United States and
11 to violate the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 353, violating anti-kickback laws,
12 and “using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids—
13 frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged America
14 for decades.”
15

16 495. The new plea agreement does not identify Purdue’s co-conspirators, and McKinsey
17 is not identified by name in the agreement. Instead, McKinsey is referred to as the “consulting
18 company.”
19

20 496. Purdue’s new guilty plea concerns Covered Conduct (as defined in the plea
21 agreement) that directly implicates McKinsey in the conspiracy. It is the same conduct described
22 in this Complaint.

23 497. Indeed, the plea agreement signed by McKinsey’s co-conspirator states bluntly:
24 “Purdue, *in collaboration with [McKinsey]*, implemented many of [McKinsey’s]
25 recommendations.” (emphasis added).
26
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1 498. Further, Purdue admitted that E2E “*was overseen by [McKinsey]* and some of
 2 Purdue’s top executives through the creation of the E2E Executive Oversight Team (‘EOT’) and
 3 Project Management Office (‘PMO’)” (emphasis added).

4 **ii. A Mea Culpa**

5 499. On December 5, 2020, six weeks after Purdue’s second guilty plea, McKinsey
 6 issued a rare public statement regarding its work with a specific client on its website. The client
 7 was Purdue, and the statement was issued in response to Purdue’s second guilty plea and recent
 8 media reports regarding McKinsey’s work selling OxyContin after 2007:
 9

10
 11 **McKinsey statement on its past**
 12 **work with Purdue Pharma**
 13

14 *December 5, 2020—As we look back at our client service during the opioid crisis, we recognize*
 15 *that we did not adequately acknowledge the epidemic unfolding in our communities or the terrible*
 16 *impact of opioid misuse and addiction on millions of families across the country. That is why last*
 year we stopped doing any work on opioid-specific business, anywhere in the world.

17 Our work with Purdue was designed to support the legal prescription and use of opioids for
 18 patients with legitimate medical needs, and any suggestion that our work sought to increase
 19 overdoses or misuse and worsen a public health crisis is wrong. That said, we recognize that we
 have a responsibility to take into account the broader context and implications of the work that we
 do. Our work for Purdue fell short of that standard.

20 We have been undertaking a full review of the work in question, including into the 2018 email
 21 exchange which referenced potential deletion of documents. We continue to cooperate fully with
 the authorities investigating these matters.

22 500. As the statement indicates, McKinsey stopped doing work “anywhere in the world.”
 23 Given that Purdue’s operations addressed only the United States, the global reach of McKinsey’s
 24 regret is noteworthy.

25 501. In August 2013, when the Sacklers adopted McKinsey’s “Project Turbocharge” for
 26 Purdue, Tim Reiner, a long-time McKinsey consultant, joined Mundipharma. Mundipharma is a
 27 separate company—also owned by the Sacklers—that sells opioids internationally.
 28

502. As late as 2019, Mundipharma has been asserting many of the same misleading claims about opioids that previously led to criminal liability in the United States.³⁵⁸ McKinsey has long assisted the Sacklers in growing Mundipharma's opioids market.³⁵⁹ By 2015, McKinsey's workload with Mundipharma was large enough to merit formal coordination and incorporation with the overall McKinsey team servicing the Purdue account. Around this time, McKinsey's Elling agreed to assume "a real operational DCS" role with respect to the work that McKinsey was performing for the various Sackler interests, including "integrat[ing] the Mundipharma stuff."³⁶⁰ Even if the various components of the Sackler "family conglomerate" were nominally independent, McKinsey consolidated its own treatment of its work for all of these companies as serving just a single client.

iii. A Hedge Fund

503. On February 4, 2021, forty-nine state attorneys general announced a multistate settlement with McKinsey related to its work for opioid manufacturers. McKinsey agreed to pay almost \$600 million dollars. At the time of the announcement, most of the participating states each filed a complaint and consent decree finalizing the settlement.

504. Three days after the settlement, it came to light that McKinsey appears to have benefitted from its work promoting opioids not only through the fees paid to McKinsey by its clients, but also through investments in opioid-related business made by McKinsey's own hedge fund, the McKinsey Investment Office ("MIO"). MIO is the hedge fund referenced above, with respect to McKinsey's investment in Teva Pharmaceutical.

³⁵⁸ See Kinetz, Erika, *Fake doctors, pilfered medical records drive OxyChina sales*, Associated Press, November 19, 2019, available at: <https://apnews.com/article/4122af46fdb42119ae3db30aa13537c>

³⁵⁹ See, e.g., MCK-MDL2996-0256120; MCK-MDL2996-0327127; MCK-MDL2996-0183279; MCK-MDL2996-0238998; MCK-MDL2996-0286490.

³⁶⁰ MCK-MDL2996-0210149

1 505. Consultants don't typically have in-house hedge funds overseeing retirement
 2 accounts and partners' personal investments. In fact, McKinsey is the only one. "Most large
 3 companies, including all the major consulting firms, hire third-party firms . . . to oversee their
 4 employees' retirement accounts."³⁶¹ MIO manages approximately \$31 billion on behalf of
 5 McKinsey partners, employees, and former partners.³⁶²

6
 7 506. Through MIO, McKinsey was heavily invested in the opioid industry, and stood to
 8 gain financially from the continuation of the opioid crisis. It even invested in opioid addiction
 9 treatment businesses—a growing industry, as McKinsey knew.

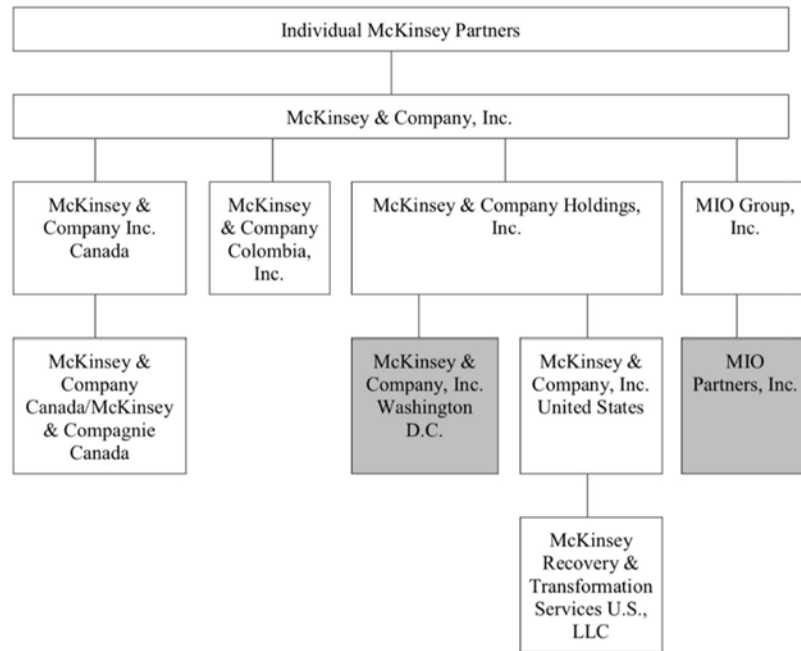
10 507. In short, "during the years McKinsey was helping opioid makers propel sales of the
 11 drugs, MIO Partners held stakes in companies that profited from increased usage."³⁶³

12 508. To understand MIO, an organizational chart of McKinsey is helpful:
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25 ³⁶¹ Gretchen Morgenson, "Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from
 treating addicts.," *NBC News*, February 8, 2021, *available at* <https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969>

26 ³⁶² SEC Order dated November 19, 2020 at Para. 5, *available at*: <https://www.sec.gov/litigation/admin/2021/ia-5912.pdf>. That \$31 billion under management would make MIO Partners the thirteenth largest hedge fund on Earth.
 27 *See* <https://www.pionline.com/interactive/largest-hedge-fund-managers-2021>.

28 ³⁶³ Gretchen Morgenson, "Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from
 treating addicts.," *NBC News*, February 8, 2021, *available at* <https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969>



509. MIO Group, Inc., and MIO Partners, Inc. are directly-owned subsidiaries of McKinsey & Company, Inc. Given that McKinsey advises countless large corporations, McKinsey's hedge fund inevitably invests in McKinsey's clients.

510. MIO manages money for pension plans sponsored by McKinsey in which current and former McKinsey employees participate, as well as privately-offered investment funds available to partners and former partners. Today, nine of MIO's eleven directors are current or former McKinsey partners. Prior to 2017, there were no outside directors at MIO.

511. MIO structures its investment activities in three principal ways: (1) approximately 50-60% of MIO's assets are managed by third-party money managers, who have sole discretion on what securities to buy with MIO's money, and where MIO may or may not have information regarding which securities the third-party money manager has purchased for MIO's benefit; (2) "separately managed accounts," comprising approximately 40% of MIO's holdings, are portfolios of securities managed by a third-party money manager, but where MIO "knows what securities are held through each account," and; (3) direct investments, where MIO invests its own money directly, which comprises approximately 10% of MIO's investments.

1 512. In other words, for *at least 40%* of MIOs holdings, McKinsey partners are able to
2 know the specific investments held by the various MIO funds. “MIO has a ledger for every security
3 in their managed accounts.”³⁶⁴ That comprises a pool of capital worth more than \$6 billion.

4 513. MIO is run for the benefit of McKinsey’s partners and, to a separate extent,
5 McKinsey’s employees. Those individuals (and, crucially, former McKinsey partners) invest their
6 own money in MIO, and their access to those investment opportunities constitutes a meaningful
7 and important component of those individuals’ compensation. MIO has, “at a minimum, the ability
8 to view the individual securities that account for approximately 40 to 50 percent.” This is
9 approximately \$6 billion dollars of invested capital. What is more, MIO *directly invests*
10 approximately 10% of its assets. That is \$1.5 billion MIO directly invests in securities without the
11 use of any outside money manager. These numbers exclude leverage.

12 514. From a conflicts perspective, the fact that *former* partners may participate in MIO
13 investments merits consideration. With respect to McKinsey’s opioid investments, it is notable to
14 consider just who some of those “former partners” are. As noted above, Rajiv de Silva, Chief
15 Executive Officer of opioid defendant Endo Pharmaceuticals, is a former McKinsey partner. Kare
16 Shultz, Chief Executive Officer of opioid defendant Teva Pharmaceutical, is a former McKinsey
17 partner. Frank Scholz, President of opioid defendant SpecGX, a subsidiary of Mallinckrodt, is a
18 former McKinsey partner. Marc Owen, President of opioid defendant McKesson, is a former
19 McKinsey partner. This list is merely illustrative; it is not exhaustive.

20 515. The result is the prospect of individual executives at various opioid manufacturing
21 and distribution companies obtaining financial gain from the ongoing propagation of the opioid
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28 ³⁶⁴ Michelle Celarier, *McKinsey’s Managed Accounts Come Under Scrutiny in Trial*, Institutional Investor, February
5, 2020, *available at*: <https://www.institutionalinvestor.com/article/b1k6wnn251s472/McKinsey-s-Managed-Accounts-Come-Under-Scrutiny-in-Trial>

1 crisis *not* via compensation from their employers, but via participating in investments alongside
 2 their *former* employer (and, in many cases, current consultant).

3 516. Three days after McKinsey and the state attorneys general announced their
 4 settlement, NBC News reported that MIO, McKinsey's hedge fund, owned opioid-related
 5 investments during the time that it advised its opioid clients.
 6

7 517. One is Deerfield Management Co., "a \$10 billion dollar health care investment firm
 8 based in New York."³⁶⁵ As ever, "two top Deerfield executives previously worked at McKinsey."
 9 A retirement fund managed by MIO held a \$108 million stake in funds managed by Deerfield and
 10 invested in opioid industry participants. "In 2017, for example, Deerfield was a 6 percent
 11 shareholder in Mallinckrodt, a major opioid maker."³⁶⁶ From 2011 through 2016, Deerfield held a
 12 stake of up to \$90 million in Teva. Deerfield also took stakes in the distributors described above,
 13 including McKesson and Cardinal Health.³⁶⁷
 14

15 518. McKinsey is also invested in treatment, an inevitable growth industry sprouting
 16 from the over-selling of opioids. Separate from its investments with Deerfield, MIO is also invested
 17 in Adamis Pharmaceuticals, "a company that develops products to treat opioid overdoses," and
 18 therefore "may also benefit from opioid settlement funds" paid by McKinsey as a result of its
 19 settlement with the states. As of 2020, MIO owned 26% of the Adamis' preferred shares through
 20 another outside investment manager (not Deerfield).³⁶⁸ Separately, Deerfield invested \$331 million
 21 in Recovery Centers of America, an addiction treatment company that operates facilities in states
 22 that McKinsey recently settled with.³⁶⁹
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25 ³⁶⁵ Gretchen Morgenson, "Consulting giant McKinsey allegedly fed the opioid crisis. Now an affiliate may profit from
 26 treating addicts.," *NBC News*, February 8, 2021, *available at* <https://www.nbcnews.com/news/us-news/consulting-giant-mckinsey-allegedly-fed-opioid-crisis-now-affiliate-may-n1256969>

27 ³⁶⁶ *Id.*

28 ³⁶⁷ *Id.*

³⁶⁸ *Id.*

³⁶⁹ *Id.*

1 519. These relationships and investments give a glimpse into the myriad means
2 McKinsey deploys to make money. Consulting is more than giving advice. Indeed, On November
3 19, 2021, MIO Partners agreed to pay an \$18 million fine to the SEC due to MIO's possession of
4 material nonpublic information related to its holdings, information obtained through consulting.

5
6 **i. Publicis: “The Power of One”**

7 520. Defendant Publicis Health is an advertising and consulting company that services
8 pharmaceutical manufacturers. Publicis Health is a division of the French multi-national
9 advertising and communications conglomerate Publicis Groupe, S.A. (“Publicis”). Annual
10 revenues exceed \$9 billion annually.

11 521. Publicis is one of the “Big Four,” as the four firms that account for more than half
12 of the global advertising industry are called.³⁷⁰ In 2002, as the opioid crisis was taking root across
13 the United States, the president of the American Association of Advertising Agencies, stated, “Now
14 you have four megacompanies with revenues that are staggering, bigger than some of the
15 companies they serve.”³⁷¹

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17 522. The rise of the Big Four came through decades of mergers and acquisitions of
18 separate agencies and industry consolidation; each is essentially a conglomerate. For its part,
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23 ³⁷⁰ The other three are Omnicom Group, the Interpublic Group of Companies, and the WPP Group. Stuart Elliott,
24 Advertising's Big Four: It's Their World Now, *New York Times*, March 31, 2002, available at:
<https://www.nytimes.com/2002/03/31/business/advertising-s-big-four-it-s-their-world-now.html>

25 Other primary vendors to large companies have their own little linguistic conferences. For advertising's Big Four,
26 consulting has its Big Three – also referred to as “MBB” – comprised of McKinsey, Bain, and Boston Consulting
27 Group. See [https://en.wikipedia.org/wiki/Big_Three_\(management_consultancies\)](https://en.wikipedia.org/wiki/Big_Three_(management_consultancies)). The Big Four and the Big Three
increasingly compete for the same project work at the same clients. Moreover, accountancies have their own Big Four,
and compete with the Big Three and the other Big Four. See https://en.wikipedia.org/wiki/Big_Four_accounting_firms.
These Big vendors provide services demanded by thousands of overlapping clients. That market reality confers
substantial power to this Big, elite few.

28 ³⁷¹ Stuart Elliott, Advertising's Big Four: It's Their World Now, *New York Times*, March 31, 2002, available at:
<https://www.nytimes.com/2002/03/31/business/advertising-s-big-four-it-s-their-world-now.html>

Publicis grew by acquiring the agencies Fallon McElligott, Saatchi & Saatchi, and Nelson Communications, among many others.³⁷²

523. Today, Publicis operates numerous subsidiaries focusing on subsets of the advertising industry. Publicis Health is the conglomerate's division that specializes in work for healthcare and pharmaceutical companies. Within Publicis Health, there at least fifteen "agency brands" – subsidiaries, essentially, operating under their own brand names. Each provides specialized advertising and communications strategies to Publicis' pharmaceutical clients. Razorfish Health, Publicis Health Media, Digitas Health, Rosetta, and Verilogue are some examples.³⁷³

524. Each brand specializes in a specific niche within the overall suite of sales and marketing services offered by Publicis Health. Razorfish pioneered and specializes in digital marketing; Digitas specializes in interactive marketing; Publicis Health Media's wheelhouse has been creative and media marketing. Verilogue's niche is providing audio recordings of interactions between patients and doctors that may be mined for insights on how to sell more drugs. Routinely, a Publicis client would engage with more than one of its subsidiaries in tandem and as part of an overall client relationship with Publicis.³⁷⁴

525. Until 2019, Publicis also owned Publicis Touchpoint Solutions, which provided contract sales organization ("CSO") services to pharmaceutical manufacturer clients.³⁷⁵ Pharmaceutical companies routinely seek to optimize their salesforces to maximize profitability.

³⁷² Stuart Elliott, Advertising's Big Four: It's Their World Now, *New York Times*, March 31, 2002, available at: <https://www.nytimes.com/2002/03/31/business/advertising-s-big-four-it-s-their-world-now.html>

³⁷³ See <https://publicishealth.com/companies>.

³⁷⁴ For example, upon information and belief, Purdue used Publicis Health Media and Razorfish during the same year, and paid separate invoices to each agency, despite their joint ownership.

³⁷⁵ On January 31, 2019, Publicis Healthcare Solutions, formerly known as Publicis Touchpoint Solutions, was sold by Publicis Groupe to Altamont Capital Partners. See "Altamont Capital Partners Acquires Publicis Healthcare Solutions," January 31, 2019, available at: <https://www.prnewswire.com/news-releases/altamont-capital-partners-acquires-publicis-healthcare-solutions300787750.html#:~:text=Altamont%20Capital%20Partners%20Acquires%20Publicis%20Healthcare%20Solutions>

1 As such, the typical pharmaceutical company does not maintain under-utilized salesforces, or
2 salesforces larger than necessary to maximize revenue on the company's current product offerings.
3 The result, oftentimes, is that a pharmaceutical company hoping to launch a new product will not
4 have the resources in-house to adequately push a new product launch.

5
6 526. Publicis Touchpoint Solutions solved these problems for clients by offering contract
7 salesforces to augment the number of sales representatives a manufacturer can deploy in order to
8 maximize the success of a product launch. Or, in many cases, Publicis would employ and control
9 the entire sales force for a given drug, on a contract basis, for drug manufacturers that wish to
10 outsource the entirety of their sales and marketing efforts.³⁷⁶ As will be seen, Publicis Touchpoint
11 Solutions provided sales representatives to numerous opioid manufacturers for numerous opioid
12 products at different stages of the product life cycle.

13
14 527. These different divisions offering complementary services to clients function as a
15 seamless whole. "'The Power of One' is Publicis Groupe's operating philosophy. Bringing together
16 80,000 employees across more than 110 countries and 56 agency brands, we deliver a seamless and
17 modular experience in the relentless service of our clients," Publicis says.³⁷⁷ That seamless and
18 modular experience is "free from silos," with "unified P&L's" and no operational barriers between
19 Publicis' brands.³⁷⁸

20
21 528. "The Power of One" is more than marketing pabulum. It governs the operations of
22 the parent organization and how it exerts control over its numerous agencies. This control can at
23 times lack subtlety. "Publicis Groupe executives gathered a few months ago to debate which agency
24 would service a new piece of business won by the holding company's centralized Power of One

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27 ³⁷⁶ While the new product launch is a classic use case for a CSO, is it's not their only use. A drug manufacturer may
also choose to utilize a CSO at other stages of the product life cycle, for instance as loss of exclusivity approaches and
a manufacturer wishes to re-deploy its internal sales force to focus on newer drugs or those about to be launched.

28 ³⁷⁷ See <https://publicishealth.com/companies>.

³⁷⁸ See <https://www.publicisgroupe.com/en/the-groupe/about-publicis-groupe>

1 team, which is composed of talent from its various shops. According to a person at the meeting – a
 2 former creative from a Publicis agency – a suggestion was made for the assignment to be handled
 3 out of Saatchi & Saatchi New York. According to that creative, one of Publicis’ CEO-Chairman
 4 Arthur Sadoun’s ‘main people’ responded: ‘Don’t put that there; [Saatchi] won’t be here next
 5 year.’”³⁷⁹

6
 7 529. By October of 2021, Publicis had risen to become the largest advertising
 8 conglomerate in the world, with a market capitalization of a little more than \$16 billion.³⁸⁰

9 **j. What Publicis Does: Marketing and Consulting**

10 530. Traditionally, the advertising industry organized itself based on the “agency model,”
 11 with advertising agencies performing both creative and advertising placement services. At the top
 12 of the pyramid was the “agency of record,” or “AOR.” The AOR is the advertising agency
 13 appointed by the client to coordinate the purchase of media time and space for the placement of
 14 client advertisements. While any given client may choose to employ multiple advertising agencies
 15 to assist with specific projects, the AOR sits atop those other agencies performing project work and
 16 directs the placement of project work performed by other agencies for the client. Typically, the
 17 AOR will receive payment from an agency performing project work for the client for its
 18 placement.³⁸¹ Given its control over the placement of client content – in effect, a monopoly on the
 19 client marketing distribution channel – the AOR was in a position to influence the conduct of other
 20 contracting agencies performing discrete projects for the client, should the client choose to utilize
 21 different agencies for different marketing functions (digital vs. print media, for example).
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 27 ³⁷⁹ Lindsay Rittenhouse, “Uncertainty Over Future Direction of Publicis Triggers Employee Unrest – And Talent Exodus,” *Ad Age*, January 16, 2020, available at: <https://adage.com/article/agency-news/uncertainty-over-future-direction-publicis-triggers-employee-unrest-and-talent-exodus/2226346>

28 ³⁸⁰ See <https://www.prweek.com/article/1731568/publicis-overtakes-rivals-worlds-valuable-agency-group>

³⁸¹ See https://www.allbusiness.com/barrons_dictionary/dictionary-agency-of-record-4962111-1.html

531. Publicis' various divisions performed multiple roles for various opioid manufacturers, including AOR roles on numerous campaigns as well as project work under the aegis of other AORs. Publicis' Rosetta, for example, [REDACTED]

[REDACTED] Publicis' Saatchi & Saatchi Healthcare [REDACTED]

532. The traditional AOR model has evolved significantly over the years as a result of consolidation within the industry, as well as competition from without. As the marketing industry has consolidated into the Big Four, it has transformed its product offerings in response to competition from consulting firms. The result is that Publicis has outgrown its heritage and is now far more than an advertising agency. It has transformed into an offeror of strategy and consulting services in addition to traditional agency work.³⁸³

533. In response to competition from outside the traditional agencies, coupled with the expansion of traditional advertising channels to encompass new technologies, the rise of digital marketing, the erosion of traditional print mediums, and other market dynamics, the Big Four agencies have evolved in recent years beyond the traditional AOR hierarchy to offer services to their clients in more nuanced and flexible ways, and to pair traditional product offerings with newer services.

k. A Consulgency

534. Publicis is no exception; indeed, it is an exemplar of these industry trends.

535. These days, Publicis is not just a content creator and placement agent; it is also a consultant. Indeed, the evolution of management consulting and advertising (and *particularly* pharmaceutical advertising) has created a market reality in which there is substantial overlap in the product offerings of global advertising agencies like Publicis and global management consultants

³⁸² Transcript of Amanda Stephens Hogan Deposition dated January 25, 2019, Pg. 414:3-8,

³⁸³ For example, Publicis Sapient's Strategy & Consulting Practice Group describes its approach, "Our strategy and consulting teams work seamlessly with our experience and engineering teams to ensure we develop the most high-impact strategies to drive effective digital business transformation."

1 like McKinsey & Company, Inc. Just as McKinsey's traditional management consulting business
 2 has evolved to encompass various operational roles performed for clients, including sales and
 3 marketing design and implementation, the traditional advertisers have similarly evolved.

4 536. Publicis, for example, evolved to offer strategy consulting services and perform
 5 implementation work in addition to merely proposing advertising campaigns. By 2018, Publicis'
 6 investor presentation emphasized this shift, declaring that "We have the organization to *shift* from
 7 a **communications** partner to a **transformation** partner."³⁸⁴ The goal of any Publicis client
 8 relationship is to "be our clients' indispensable partner in their transformation."³⁸⁵

9 537. This is part of a broader shift in the overall consulting and marketing industries.
 10 "Traditionally, marketing agencies spoke to the Chief Marketing Officer and implemented
 11 communication strategy, while consultants spoke with the CEO and devised the general strategy –
 12 with marketing communications being the tail of it. In an effort to compete, agencies have started
 13 to develop consulting skills, creating 'consulgencies.'"³⁸⁶ As an example, Publicis' Publicis Sapient
 14 division was ranked in 2019 as the premier leader in providing "digital transformation" services,
 15 besting traditional consultants Accenture, Ernst & Young, PwC, and McKinsey.³⁸⁷ According to
 16 the rankings analysis, these digital transformation leaders "blend strategy and execution chops and
 17 couple them with the soft skills for inspiring leadership and training teams," and identified Publicis
 18 as "the top consultancy on the customer experience front" and "an especially strong partner where
 19 the transformation emphasis is on creating world-class digital customer and employee
 20 experiences."³⁸⁸

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 25 ³⁸⁴ Publicis Groupe Investor Day Presentation dated March 20, 2018, *available at*:
<http://documents.publicisgroupe.com/events/2018-03-investor-day-intro.pdf> (emphasis in original).

26 ³⁸⁵ *Id.*

27 ³⁸⁶ "Agencies, consulting firms, and the future of marketing," *Rewire Mag*, *available at*: [https://rewire.ie.edu/agency-](https://rewire.ie.edu/agency-vs-consulting-firms-future-marketing/)
[vs-consulting-firms-future-marketing/](https://www.consulting.us/news/1991/publicis-sapient-named-a-leader-in-digital-transformation)

28 ³⁸⁷ <https://www.consulting.us/news/1991/publicis-sapient-named-a-leader-in-digital-transformation>

³⁸⁸ "Publicis Sapient named leader in digital transformation," *Consulting.us*, March 21, 2019, *available at*:
<https://www.consulting.us/news/1991/publicis-sapient-named-a-leader-in-digital-transformation>. Firms like Razorfish

538. One marketing executive, upon his company being acquired by a large consulting firm, explained, “we see the next decade as belonging to what we call ‘consulencies’ – offerings at the cusp of what consultancies do and agencies do – bringing the best of both worlds together.”³⁸⁹ One benefit of this hybrid model is greater access to client information than a traditional agency model would entail. “I think consultancies are allowed more to look at the business side of things than agencies. Clients are not willing to share confidential information with us,” explained one marketing professional.³⁹⁰

539. A natural outcome of this convergence between the management consulting and advertising industries has been partnerships between incumbent management consultants and incumbent agencies as both find themselves competing for the same business in a new competitive landscape.

540. Publicis and McKinsey routinely partner on projects together for mutual clients.

541. “McKinsey & Company and Publicis Health work together to help clients develop agile approaches to winning launches,” declaimed a pharmaceutical industry marketing publication.³⁹¹ In 2016, Janet Winkler, then a Group President at Publicis Health³⁹², and Brian Fox,

and Sapient were seen as competitors to McKinsey from the outset, as McKinsey was experiencing a wave of employee departures during the early 2000’s. “It wasn’t just dot-com startups that were alluring. A whole new class of consulting firm burst onto the scene, with hipper names – Razorfish, Scient, Viant, and Sapient – and sexier projects. The work they were doing seemed far more crucial than redrawing organizational charts. They were helping companies use the Internet to transform everything about the way they did business – from sourcing to distribution to how they treated and served their customers.” Duff McDonald, *The Firm*, Pg. 265. Razorfish, Scient, and Sapient were eventually acquired by Publicis. (Viant, which was *not* scooped up by one of the Big 4, was instead acquired in 2002 by a company named Divine that liquidated in bankruptcy the following year.)

³⁸⁹ “The deal that unlocks the value of our industry,” *Marketing Magazine*, June 8, 2018, available at: <https://marketingmagazine.com.my/arrival-of-the-consulgency/>

³⁹⁰ Shareen Pathak, “‘We’re giving the business away to consultants’: Agencies brace for new competition,” *Digiday*, October 25, 2017, available at: <https://digiday.com/marketing/giving-business-away-consultants-agencies-brace-new-competition/>

³⁹¹ Janet Winkler, Brian Fox, et. al. “Five Inconvenient Truths That Can Make or Break a Product Launch,” PM360, November 23, 2016, available at: <https://www.pm360online.com/five-inconvenient-truths-that-can-make-or-break-a-product-launch/>

³⁹² In 2017, Winkler left her role as Group President of Publicis. The following year, she joined McKinsey & Company as a Senior Advisor.

1 a Senior Partner at McKinsey, co-authored the article “Five Inconvenient Truths That Can Make
2 or Break a Product Launch” in industry trade publication PM360.

3 542. McKinsey and Publicis co-authored³⁹³ the piece to highlight their joint expertise in
4 pharmaceutical marketing. “Applying complementary tool and capabilities, [McKinsey and
5 Publicis Health] deliver rapid, actionable analytics as well as change management and execution
6 support to accelerate brand performance throughout the lifecycle,” explained a note accompanying
7 the article.

8
9 543. Purdue is one example, but Publicis and McKinsey had many other mutual opioid
10 manufacturer clients. They worked for these clients contemporaneously and for years while the
11 opioid epidemic grew to its present scourge.

12
13 **1. Publicis and Purdue: Selling the Sackler Strategy**

14 544. As explained in detail above, in the wake of Purdue’s 2007 guilty plea with the
15 Department of Justice and accession to a 5-year Corporate Integrity Agreement with the Office of
16 Inspector General for the United States Department of Health and Human Services, Purdue faced
17 newly imposed constraints on its sales and marketing practices. As a result, the Sackler family
18 desired to achieve distance from this “concentration of risk” by diversifying the family fortune
19 away from Purdue, and by increasing OxyContin sales in the near term in order to achieve that
20 distance.

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26 ³⁹³ In addition to Winkler and Fox, “Gregory Graves, Associate Partner, McKinsey & Company; Catherine Mayone,
27 EVP, General Manager, Publicis Health and Sapient Health; and Dan Tinkoff, Partner, McKinsey & Company, also
contributed to this article.” See <https://www.pm360online.com/five-inconvenient-truths-that-can-make-or-break-a-product-launch/>

28 Notably, the McKinsey authors – Fox, Graves, and Tinkoff – [REDACTED]

1 545. Alongside McKinsey, Publicis was integral to the sales and marketing campaigns
 2 deployed to increase OxyContin sales notwithstanding the Corporate Integrity Agreement and in
 3 furtherance of the Sacklers wishes.³⁹⁴

4 **i. Hopelessly dependent on consultants; “Desperately seeking new growth.”**

5 546. Purdue was captured. After the 2007 guilty plea, the Sackler family wished to
 6 dispose of Purdue because it was concerned about both legal liability and reputational risk
 7 associated with owning the monoline opioid manufacturer. After 2007, the name of the game was
 8 profit maximization of a drug Purdue’s owners knew had no long-term future.

9 547. The company, in other words, was a basket case: pursuing internally contradictory
 10 goals to maximize opioid sales because its previous efforts to maximize opioid sales had created
 11 an existential crisis for the company. Threading a needle like that is hard. Purdue needed others to
 12 tell it what to do in order to achieve its owners’ mandate.

13 548. By the end of 2013, Purdue was seeking any opportunity to maintain growth it could
 14 identify. Publicis noted that Purdue’s Board (meaning the Sackler family) was “always looming,”
 15 and the pressure was always to increase sales. One risk Publicis identified was the risk that the
 16 Sacklers would fire the CEO at that time, John Stewart.

17 549. Publicis summed up its outlook for its client, “PURDUE in 2014: Desperately
 18 seeking new growth.”

19 550. This is red meat to consultants. McKinsey & Company. ZS Associates. Publicis.
 20 These happy warriors³⁹⁵ serviced Purdue after the company’s executives pleaded guilty in 2007,

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 26 ³⁹⁴ To emphasize the disregard with which the CIA was met, Dr. Richard Sackler has testified, incredibly, that he has never read the agreement, despite his years of continued service on Purdue’s Board of Directors before, during, and after the CIA compliance period.

27 ³⁹⁵ Consultants love martial metaphors. See “Publicis 2020: Sprint to the Future,” Publicis Groupe, March 20, 2018,
 28 available at: <https://www.publicisgroupe.com/en/news/press-releases/publicis-2020-sprint-to-the-future-en-1>
 (Publicis helping clients to “reduce their costs and win the battle with new competition); see also, “A battle plan for telcos’ digital attacker brands,” McKinsey & Co., March 5, 2021, available at:

1 and with full knowledge of that guilt.³⁹⁶ All worked for Purdue on an ongoing basis right up until
 2 Purdue stopped marketing OxyContin in 2018. And they worked *together*. They teamed up to
 3 service a client so dependent on their offerings that it could no longer function without their ongoing
 4 assistance.

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 6 551. Indeed, the consultants banded together to achieve their own goals with respect to
 7 mutual clients. “McKinsey & Company and Publicis Health work together to help clients develop
 8 agile approaches to winning launches. Applying *complementary* tools and capabilities, they deliver
 9 rapid, actionable analytics as well as change management and execution support to accelerate brand
 10 performance.”³⁹⁷

11
 12 552. As will be seen, Publicis’ complementary tools and capabilities were critical to
 13 McKinsey’s *Project Turbocharge*, which was adopted by Purdue and implemented by all three (and
 14 ZS) in late 2013 and thereafter.

15 **ii. Branded Marketing**

16 553. Purdue was a monoline manufacturer of opioids. OxyContin (oxycodone), Hysinglia
 17 (hydrocodone), Targiniq (oxycodone/naloxone) and Butrans (buprenorphine) were Purdue’s
 18 principal branded opioid products. Publicis worked on campaigns for all four. But OxyContin was
 19 the cash cow. As Publicis’ Rosetta unit described it in 2014, “for 17 years Purdue has relied almost
 20 solely on the revenue from their \$3b blockbuster opioid medication, OxyContin (~90% of Purdue’s
 21 revenue).”
 22

23
 24 <https://www.mckinsey.com/industries/technology-media-and-telecommunications/our-insights/a-battle-plan-for-telcos-digital-attacker-brands>;

25 ³⁹⁶ For example, an internal Publicis Client Service Team review document prepared in 2013 for the Purdue account
 26 began with a section entitled, “To know Purdue,” which stated, “In 2007, John Brownlee U.S. Attorney charged that
 27 ‘Purdue, under leadership of its top executives, continued to push a fraudulent marketing campaign... In the process
 scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a
 drug that Purdue led many to believe was safer, less abusable and less addictive than other pain medications on the
 market.”

28 ³⁹⁷ Janet Winkler and Brian Fox, “Five Inconvenient Truths That Can Make or Break a Product Launch,” PM360,
 November 23, 2016, *available at*: <https://www.pm360online.com/five-inconvenient-truths-that-can-make-or-break-a-product-launch/> (emphasis added).

554. The Publicis-Purdue relationship began as early as April 2010, during the pendency of the 5-year Corporate Integrity Agreement to which Purdue was bound as a result of its 2007 guilty plea, when Rosetta Marketing Services LLC entered into a Master Services Agreement to work on OxyContin and other Purdue opioids.³⁹⁸ The Purdue relationship lasted as late as 2019.

555. As one industry trade journal described the relationship, “Rosetta’s unique role lies in developing personalized marketing program built on consumer insights, as in the agency’s integrated campaigns for... Purdue’s pain drug OxyContin and pain patch Butrans”³⁹⁹

1. OxyContin

556. From the outset of the Purdue relationship in 2010, Publicis entities, beginning with Rosetta, were Covered Persons⁴⁰⁰ pursuant to the Corporate Integrity Agreement Purdue was then bound by, and which remained in effect until May 2013.

a. *Project Turbocharge a/k/a Evolve to Excellence a/k/a E2E*

557. Within a few *months* of its expiration, and with the CIA now out of the way, McKinsey proposed, and Purdue adopted, *Project Turbocharge*, a sweeping effort to revitalize OxyContin sales by overhauling and empowering Purdue’s sales force to deliver in a precision-targeted way new messaging regarding OxyContin. Purdue adopted McKinsey’s recommendations, coordinated with McKinsey to implement the recommendations, and immediately involved Rosetta in doing so. As a sign of the transformative nature of the undertaking, the project was unveiled as the theme of Purdue’s 2014 national sales campaign.

³⁹⁸ Publicis acquired Rosetta in May of the following year for \$575 million. *See* Eric Pfanner, “Publicis to Acquire Rosetta for \$575 Million,” *New York Times*, May 17, 2011, *available at*: <https://www.nytimes.com/2011/05/18/technology/18iht-publicis18.html>

³⁹⁹ Marc Iskowitz, “100 Agencies: Rosetta – Acquisition by Publicis, integration activities lead to flat year for agency,” *Medical Marketing and Media*, July 1, 2012, *available at*: <https://www.mmm-online.com/home/channel/features/100-agencies-rosetta/>

⁴⁰⁰ The relevant language in the Corporate Integrity Agreement provides: “‘Covered Persons’ includes . . . all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions . . . on behalf of Purdue.”

1 558. On Saturday, September 28, 2013, [REDACTED]

2 [REDACTED]
3 [REDACTED] he
4 explained.⁴⁰¹ [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]

10 559. [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]⁴⁰⁴

16 560. From the outset, Rosetta was an integral partner in shaping what McKinsey's
17 program would become. By the end of the first month of *Project Turbocharge*, Rosetta was working
18 to assemble, ratify, and finalize informational streams from other consultants regarding targeting
19 healthcare providers with new OxyContin messaging. [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

23 [REDACTED] The additional work included [REDACTED]
24
25

26 ⁴⁰¹ PPLPC018000873870.

27 ⁴⁰² PPLPC018000873870. "ADF" is an acronym for "abuse deterrent formulation," i.e., the reformulated OxyContin
that was crush-resistant. ADF is addressed further in this Complaint, below.

28 ⁴⁰³ PPLPC018000873870.

⁴⁰⁴ PPLPC018000873870.

⁴⁰⁵ PPLPC018000885202

1 [REDACTED]
 2 [REDACTED]
 3
 4 561. Internally, Rosetta envisioned itself as perhaps playing an *even more* central role in
 5 McKinsey's *Project Turbocharge* at Purdue than it actually did. Rosetta described itself in an
 6 internal presentation as the "strategic backbone" of Purdue's marketing efforts, including *Evolve*
 7 *to Excellence*, which Rosetta identified as one of the definitive characteristics for "success" at
 8 Purdue in 2014.⁴⁰⁷

9 562. Whether backbone or limb, Rosetta was present at the creation.⁴⁰⁸ The following
 10 sections describe certain components of Rosetta's work on *Evolve to Excellence* (or *E2E*, f/k/a
 11 *Project Turbocharge*). The conduct described is not exhaustive of Rosetta's (or Publicis') work in
 12 conjunction with McKinsey and for Purdue relating to *E2E* and adjacent projects. It is merely
 13 illustrative.
 14

15 **b. Titration and Length of Therapy**

16 563. If you sell drugs to people, there are two ways to sell more drugs. One is to start
 17 selling the drug to someone who wasn't using it before (or, to use the lingo, a "new patient start").
 18 The other way is to sell more of it to the people already using it. Titration and Length of Therapy
 19 ("LoT") efforts are directed at the latter opportunity. Stronger pills made more money; the higher
 20 the dosage strength for any individual OxyContin prescription, the greater the profitability for
 21 Purdue. Publicis went to great lengths to quantify the money to be made from increasing the length
 22
 23
 24

25 ⁴⁰⁶ PPLPC018000885202

26 ⁴⁰⁷ McKinsey's name, "Project Turbocharge" was seen as perhaps too crass or off-tone by Purdue. At a minimum, it
 27 was not "permanently appropriate." CEO John Stewart wrote to McKinsey partners Rob Rosiello and Arnab Ghatak
 28 on August 15, 2013: "Paolo Costa was especially engaged in the discussion and he (among others) will be a champion
 for our moving forward with a comprehensive 'turbocharge' process – *though we do need to find a better and more*
permanently appropriate name." (emphasis added). They settled on the decidedly more anodyne "*Evolve to*
Excellence," (or "*E2E*").

⁴⁰⁸ See Dean Acheson, *Present at the Creation: My Years in the State Department*, W.W. Norton, (1969).

of therapy. According to their calculations, an increase of 1% in average LoT for yearly unique patients represents \$20 million in additional revenue to Purdue:

From: Ben Meck <ben.meck@rosetta.com>
 Date: Tuesday, August 19, 2014 at 11:09 PM
 To: John Dwyer <john.dwyer@rosetta.com>
 Subject: RE: ERO/OxyContin slide deck

Okay, I can adjust based off this.

- Which do you like better? Since you might be presenting
 - o Every increase of 1% for average LoT for yearly unique patients (from 125.3 days on therapy to 126.6 days on therapy) is \$20M potential
 - o Every increase of 1 day for average LoT for yearly unique patients (from 125.3 days on therapy to 126.3 days on therapy) is \$16M potential
- Money point that I can include on the slide
 - o Increasing average LoT by 2.5% for yearly unique patients (from 125.3 to 128.4 days on therapy) is \$50 million potential

Ben Meck
 Manager | Analytics & Optimization
 Office +1 347.332.7655 Mobile +1 917.754.0041
 99 Hudson Street, 11th Floor, New York, NY 10013, USA
 Rosetta.com
 Rosetta. Unlock and Activate™ Human Behavior.

564. Of course, higher dosage strength and increased lengths of therapy also contribute to opioid dependency, addiction and abuse. But Publicis was there to focus on selling higher strength dosages of OxyContin, and ROI was what was most important.

565. From 2012 through 2014, Publicis worked on numerous projects to design or refresh marketing campaigns to drive higher dose prescribing, for longer periods of time. In August of 2012, Publicis explained, “A strategic driver for [OxyContin] in 2013 is to drive appropriate titration and length of therapy with continuing patients. In an effort to add more emphasis to the importance of titrating to adequate analgesia... the brand team would like to create a ‘campaign’ to raise awareness.”

566. Remarkably, Publicis created two *separate* marketing campaigns: one internal, for the Purdue sales representatives to understand how important titration and length of therapy is to *Purdue* (i.e., how the messaging effects profits), and a separate one designed to deliver the broader message to prescribers.

567. In September 2013, Publicis was brought in to “refresh” the already existing *Individualize the Dose* titration campaign. The campaign had its origins around four years prior

when, on October 26, 2009, McKinsey advised the Sacklers and the Purdue board that Purdue should train its sales representatives to “emphasiz[e] the broad range of doses,” which would have the intended effect of increasing the sales of the highest (and most profitable) doses of OxyContin. McKinsey and Purdue subsequently implemented the campaign, and Publicis was brought in to do the “refresh” of the campaign in light of “an emerging market dynamic:” the decline in “mean patient dose” of OxyContin.

568. In other words, patients were buying less drugs. Publicis was brought in to reverse the decline; to “shift” the “trend”.⁴⁰⁹

BACKGROUND	
<p>ASSIGNMENT: What have we been tasked with?</p> <p>Evolve the current OxyContin creative campaign, “Individualize the Dose” to address an emerging market dynamic</p>	<p>MEASURABLE IMPACT: How are we defining success?</p> <p>Shift in trend of declining mean dose of OxyContin</p>

569. With respect to length of therapy, Publicis offered up a blunt instrument: coupons. In April of 2013, Publicis deployed an email marketing campaign, which sent out “Savings Cards” for OxyContin that could be downloaded. These coupons were known to be an effective method of encouraging patients to continue taking OxyContin for longer than they typically would otherwise.

570. The work continued into 2014 as *E2E* was being implemented, by which time Publicis was asking probing questions like, “Does a titration step lead to longer LoT?” “Does 1 titration step correlate with a higher likelihood of a 2nd titration step? And a 2nd to a 3rd, and so on?”

571. In 2017, Publicis employees discussing titration messaging knew the score. As one put it, “We know discontinuation is usually an irrelevant subject matter (the persistent mindset is, once on an ERO [Extended-Release Opioid], the only way is up.”

572. Higher doses of opioids taken for longer periods carry greater risk. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose (“MED”))

⁴⁰⁹ See 2013-09-03 Rosetta Creative Brief, cited in the Massachusetts Attorney General Complaint, Paragraph 57.

per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. The Centers for Disease Control and Prevention also recognize that higher doses of opioids tend to increase overdose risks relative to any potential patient benefit.⁴¹⁰

573. Claims that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose, are not only deceptive and misleading, they are deadly. These claims were particularly important to promotional efforts, however, because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Marketers needed to generate a comfort level among doctors to ensure the doctors maintained patients on opioids even as the high doses became necessary.

574. Publicis was ever vigilant in its protection of the titration messaging. In a June 2014 internal "Brand Overview" presentation regarding OxyContin, a Publicis employee struck out language in a draft version referring to utilizing the "lowest possible dose" because that language was contrary to the titration and length of therapy goals for the brand.

575. The vigilance paid dividends; the titration messaging worked. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than sixty milligrams per day, which converts to the ninety MED that the CDC guideline urges prescribers to "avoid" or "carefully justify."⁴¹¹

c. Targeting Patients; Targeting Prescribers

⁴¹⁰ Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>

⁴¹¹ CDC Guideline at 16.

1 576. In order to aid prescribers and to deliver the titration message, Rosetta sought to
2 differentiate and segment patients into different “types,” so that physicians might familiarize
3 themselves of instances in which titration is appropriate. In June 2014, in furtherance of the *E2E*
4 initiative, Rosetta was hired to refresh two and create a third “patient profile,” which could be left
5 behind in brochure form in healthcare providers’ offices.

6
7 577. These profiles were meant to personalize OxyContin patients in the eyes of the
8 prescriber and described the instances in which an OxyContin patient’s dosage should be changed.
9 “Maggie” is 43 years old with “significant” lower back pain. After falling at home, she begins a
10 40mg OxyContin twice daily regimen, and is then titrated up to a 60mg tablet twice daily before
11 she “reports that her pain is properly managed.” “Carol” is 51 years old and has osteoarthritis in
12 her left hip. She starts at a 15mg dose and is titrated up to 20mg dose, “with better relief of pain
13 symptoms.” “James” is 40 and his osteoarthritis is in his knee. He starts at a 10mg OxyContin dose,
14 then is doubled titrated to 15mg. After reporting that “his pain is still not well managed,” James is
15 titrated up again to a 20mg dosage, at which point he experiences “good response to his arthritic
16 pain.”
17

18 578. Notably, in none of these patient “vignettes,” as Rosetta called them, was a patient
19 ever titrated *down*. With EROs like OxyContin, the goal of titration was always ever skyward.
20 These patient vignettes were to be included alongside information about obtaining “savings cards”
21 – coupons – in order to get a discount on your OxyContin prescription. The savings cards were
22 offered because Publicis knew from experience that their use correlated with longer average length
23 of therapy for the patients that used the coupons.
24

25 579. Another patient group that Rosetta targeted were individuals already prescribed
26 short-acting opioid medications. The goal was to transition these patients to an extended-release
27
28

1 formulation for long-term management of their pain. A longer length of therapy on an ERO like
2 OxyContin is more profitable than sales of short acting opioids.

3 580. As Rosetta segmented and targeted patient types, so too did it segment and target
4 certain prescribers. It did so in order to deliver tailored messaging to targeted individuals in order
5 to maximize the goal, to [REDACTED]
6

7 581. As mentioned above, from the outset of *E2E*, Rosetta was working on identifying
8 target lists of OxyContin prescribers, [REDACTED]


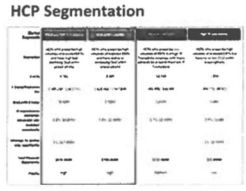
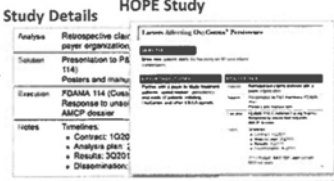
9 [REDACTED] Rosetta's targeting efforts were organized by
10 segmenting OxyContin prescribers into deciles by volume of prescriptions written.

11 582. Once these target lists were compiled, the purpose was to concentrate marketing
12 efforts on the highest decile prescribers, i.e., those doctors who were already prescribing OxyContin
13 and who, upon information and belief, had previously been subjected to Purdue's tainted marketing
14 efforts *prior* to the 2007 guilty plea.
15

16 583. At the same time, Publicis also focused marketing efforts on *new* prescribers who
17 were prescribing more OxyContin than their peers. This separate market segment of "new to brand
18 prescribers" (or "NBRx") could be plumbed for additional growth. Thus, Publicis advised sending
19 sales representatives to both "high decile prescribers" and "High-decile NBRx HCPS" up to three
20 times a month. These efforts were part of an overall initiative to generate "new patient starts"
21 (which is one way to increase sales, the other being Titration and Length of therapy, described
22 above), as set forth in an "OxyContin 2015 Tactical Planning" presentation prepared by Rosetta:
23
24
25
26
27

28 ⁴¹² PPLPC018000873870.

⁴¹³ PPLPC018000885202.

New Patient Starts		
Objective	Description	Deliverable
a) Target molecule to molecule switch from IR oxycodone to OxyContin	<ul style="list-style-type: none"> Promote molecule-to-molecule benefit as a portfolio message through reps and PTN module Resources to support molecule-to molecule switch will include Conversion/ Titration Guide, Patient Profile Vignettes & Patient Essentials Kit 	
b) Target HCPs with high NBRx share and a high oxycodone to non OxyContin switch rate	<ul style="list-style-type: none"> Segment and prioritize HCPs based on market opportunity Message on molecule-to-molecule benefits, OxyContin access, and ADP to overcome brand barriers 	
c) Educate payers on the benefits of maintaining a patient on same ERO molecule to minimize access barriers	<ul style="list-style-type: none"> Partner with a payer to study treatment patterns, opioid rotation, persistency, and costs of patients initiating OxyContin and other ER/LA opioids Develop data (HOPE study) to support messaging on molecule-to-molecule benefit 	

Produced as native document

PUBLICIS-049336

Confidential- Draft Conceptual and Theoretical Proposal for Review

584. Rosetta identified these physician targeting efforts to sell more OxyContin, which could result in more than \$1 billion of additional revenue for Purdue.

585. The targeting was not limited to segmenting physicians into deciles by volume of OxyContin prescriptions written. It also identified different physician profiles. Two patient profiles in particular were identified for targeting. The “motivated believer” was “convinced that opioid medication is essential to treatment of the chronic pain patient” and recognized OxyContin as “the leading FDA-recognized Opioid with Abused Deterrent Properties.” A “brand loyalist” was a prescriber that would remain an OxyContin prescriber despite growing concern within the medical profession regarding its abuse liability.

586. One difficult physician segment type is the “no-see.” Some physicians simply do not want to see sales representatives and will not meet with them in person. Obviously, this creates an impediment to access that pharmaceutical manufacturers seek to surmount. If you cannot

1 communicate to a physician, it is difficult to influence that individual's prescribing patterns. Rosetta
2 offered solutions.

3 587. Of course, there are other channels that can be used, such as email marketing
4 campaigns, and this Rosetta did. But there are other ways to gain access. For instance, Publicis
5 suggested that a list of all "no-see" prescribers who worked at "integrated delivery networks" be
6 compiled: "We should target anyone on the IDN Lists... regardless of decile." Rosetta and Purdue
7 then set up a call center where these prescribers who did not wish to meet with sales representatives
8 would receive phone calls instead.
9

10 588. Another response to barriers to physician access is to go around them, to talk to
11 someone else at the doctor's office instead. Rosetta designed strategies to target physician assistants
12 and nurse practitioners instead of the physicians themselves. Like the physician profiles it created,
13 Rosetta also segmented the physician assistants and nurses into "attitudinal and behavioral
14 profiles," the better with which to target OxyContin messaging, such as "dose titration
15 opportunities." In 2015, Rosetta proclaimed that these efforts to target nurses and physician
16 assistants could yield an additional 14,500 OxyContin prescriptions in the first year of
17 implementation.
18

19 589. Two years later, Publicis' efforts at targeting nurses and physician assistants
20 continued, with a Publicis employee noting the particular importance of this market segment for
21 OxyContin. In a September 27, 2016, email, she noted, "NP/Pas are a growing provider segment
22 and help offset the decline from PCPs."
23

24 590. Publicis also saw their work on targeting nurses and physician assistants as a cross-
25 selling opportunity. In 2016, Rosetta suggested Purdue hire Rosetta's affiliate, Publicis Touchpoint
26 Solutions, to deploy clinical nurse educators "trained on the Purdue sales force platform" to help
27
28

1 these nurses and PA's "understand and implement" OxyContin treatment plans and "overcome
2 behavioral obstacles that may interfere with patient adherence."⁴¹⁴

3 591. As a part of the overall implementation of *E2E*, Rosetta was involved not only in
4 delivering the marketing messages that Purdue would then deliver to healthcare providers. Rosetta
5 remained deeply involved in the actual rollout of these marketing messages. In July of 2015, three
6 Rosetta employees on the Purdue account joined sales representatives in the field for ride-alongs to
7 meet with targeted prescribers. These Rosetta employees observed in person the interactions
8 between Purdue sales representative and target prescribers during which Rosetta's messaging was
9 delivered. Rosetta was able to use the knowledge they gained from observing prescribers' reactions
10 to their messaging, which further refined their approach and maximized the effectiveness of the
11 marketing outreach.
12

13 592. These field trips served the overarching goal, as Purdue's Ron Cadet explained, to
14 [REDACTED]
15

16 **d. Non-indicated Uses**

17 593. Publicis introduced a search engine marketing "Conditions Campaign" for
18 OxyContin as early as 2013 and continued these efforts throughout the implementation of *E2E*. The
19 campaign was designed to drive prescribers conducting web searches about certain medical
20 conditions – lower back pain, for instance – to Purdue's website. "The Campaigns pertaining to
21 Conditions were the most successful out of last year's [search engine marketing] strategy and
22

23
24
25 _____
26 ⁴¹⁴ Consistent with the "Power of One" approach described supra., this was not the first time Publicis cross-sold other
27 Publicis divisions into the Purdue account. In 2015, Razorfish advised Purdue to hire Verilogue without going through
28 a competitive bidding process. This cross-selling initiative – a fine example of the "Power of One" in action – resulted
in Verilogue's analysis of patient-provider conversations being used to devise tactics to increase sales volumes of
Purdue's opioids. Verilogue's was used in furtherance of targeting and messaging goals of *E2E*, and its work was part
of the overall efforts to [REDACTED] PPLPC018000873870.

⁴¹⁵ PPLPC018000873870.

1 resulted in 25,548 Clicks, driving the most visits to PurdueHCP site,” Publicis explained in a June
2 2014 presentation.

3 594. The Conditions that Publicis targeted included low back pain, cancer pain, and
4 osteoarthritis pain. OxyContin is only approved, or indicated, to treat certain conditions, and is not
5 approved to be marketed for a non-indicated use.
6

7 595. Publicis proposed to expand the Conditions campaign to target multiple sclerosis,
8 trigeminal neuralgia, and spinal cord injury, but the proposal “raised some red flags.” John Dwyer
9 explained in an internal Publicis email, “there are search words that are disease states OxyContin
10 is not indicated for. And by having it in a document associated with OxyContin even for internal
11 review can put [Purdue] in a liability risk.” Accordingly, Publicis altered the text of the
12 advertisements that would appear when a given disease state was searched for in order to delete
13 reference to that disease state. (The ads still appeared when prescribers searched for the non-
14 indicated Conditions, the text of the ad merely referred to “that” condition, instead of a specific
15 reference to multiple sclerosis, low back pain, or the like.)
16

17 **2. Purdue’s other brands: Butrans, Hysinglia, *et. al.***

18 596. While OxyContin accounted for the lion’s share of Purdue’s revenue, the monoline
19 manufacturer sold other flavors of opioids. By the end of 2016, Publicis had won the agency of
20 record position for the rest of the Purdue’s brands as well.
21

22 597. In a 2014 presentation, [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]
27 [REDACTED]
28 [REDACTED]

⁴¹⁶ PPLPC012000477940

Rosetta has a long standing history with Purdue across multiple brands

2010 – Started as OxyContin Agency of Record for HCPs (as Wishbone)

- AOR for Partners Against Pain (PAP)
- RM program and Portal pilots for OxyContin
- Marketing Education projects
- Purdue corporate brand campaign development, corporate website, and other corporate materials

OXYCONTIN II
(OXYCODONE HCl EXTENDED-RELEASE TABLETS)



2011 – RM Management for launch of Butrans

- PurduePharma.com work, digital media planning for OxyContin

Butrans II
(buprenorphine) Transdermal System
5, 10, and 20 mcg/hour

2012 – RM Management for launch of Intermezzo

- Classwide Opioid REMS website working in partnership with McKesson (ER-LA-opioids.com)
- Purdue products' REMS website (PurdueREMS.com)

Intermezzo
(ZOPIDEEM TARTRATE) sublingual tablet
1.75 mg | 3.5 mg

2013 – Won the AOR Assignment for Targiniq ER

- Multichannel ADF Campaign evolved from prelaunch planning

TARGINIQ ER II
(OXYCODONE HYDROCHLORIDE HCl EXTENDED-RELEASE TABLETS)



2014 – RM Management and Digital Media for HYD

Publicis worked on Purdue's Butrans, Intermezzo, Targiniq, and Hysinglia brands in addition to OxyContin.

598. The same year, John Dwyer met with Purdue's Peter Justaston to discuss "Agency consolidation," and what Publicis "would need to do" to win the single Agency spot. Dwyer assured Purdue that Publicis was "up to the challenge" of being the sole Agency for all of Purdue's products. It was a goal Publicis pursued doggedly.

599. "For the last 4 years, every year as we do the forecast for the new year, I've put 'Butrans AOR business' in there under whitespace, which is where we put areas where we think we can grow," John Dwyer said to his team at Publicis in April 2016. That year, Publicis achieved Dwyer's goal, with Purdue deciding to shift some work it previously assigned to competitor agencies to Publicis' Razorfish.

600. Dwyer sent a congratulatory email on April 4, 2016, to the Publicis team about Publicis' winning additional business from Purdue, and explained that their success on the OxyContin account is what drove the decision for Purdue to award Publicis' Razorfish additional work:

... when the client told us that he was going to move the rest of the Butrans business over to Razorfish Health, the reason he said he was doing it was because he wanted up to replicate exactly everything we did last year [2015] on OxyContin. The creative campaign refresh, the visual aid that far outshone the Butrans and Hysinglia ones which were done by another agency, the strategic planning we brought them for the new competitors who are coming, and the overall revitalization of the brand... He said, "We want more like that. We want you to do the exact same thing this year, but now with Butrans."

601. The following month, Razorfish was awarded the Hysinglia account as well. Publicis' Karl Tiedemann noted in an email the "amazing relationship" developing between Purdue and Publicis, and quoted a Purdue employee as stating that the Hysinglia account was "the final piece and **we now own Purdue.**" (emphasis added).

3. Selling red herring: ADF

602. One way to keep selling opioids once widespread abuse and dependence has gripped the patient population that uses them is to introduce a new version of the drug that can be sold as "abuse deterrent." The opioid manufacturers did just that, with Purdue leading the way. Publicis was there at every step of the way to define the message and deliver it to crucial audiences: prescribers, patients, and regulators.

603. Purdue's "[abuse deterrent formulation] does not prevent abuse via swallowing," Publicis stated in a June 2014 confidential internal memorandum.

604. "As long as a drug is addictive, can be abused by swallowing higher doses, and ways to defeat the [abuse deterrent formulation] are online," no drug would ever meet the FDA's standard for "reduced abuse, misuse, and/or diversion in the community,"

1 explained former Publicis partner Ted Whitby in a June 15, 2017, email to his former colleagues at
2 Publicis.

3 605. In other words, the new formulations didn't prevent abuse. They were red herrings,
4 a distraction that an opioid manufacturer could point to in order to mollify regulators and other
5 interested parties, while knowingly not addressing the underlying abuse liabilities of their products.
6 Publicis knew this good and well, but never mind that. ADF was a message to deliver.
7

8 606. And Publicis was eager to spread the word. In July 2014 (*one month* after the internal
9 Publicis memorandum discussing the ineffectiveness of the abuse-deterrent formulation), Publicis
10 prepared the following language as a "value proposition" that sales representatives could recite to
11 doctors: "OxyContin is the only opioid that addresses the pain management needs of both patients
12 (efficacy and dosing flexibility) and society (proven abuse deterrent properties)."
13

14 607. This work was part of an ongoing project by Rosetta to get the ADF message out to
15 the world for Purdue. On March 31, 2014, as part of the overall *E2E* initiative, [REDACTED]
16 [REDACTED]
17 [REDACTED] [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED] [REDACTED]

24 608. The work proved grim. Publicis knew that the ADF messaging they were crafting
25 was misleading, but craft it they did, nonetheless. In May 2015, Publicis was working on creating
26

27 _____
28 ⁴¹⁷ PPLP0033598595

⁴¹⁸ PPLP0033598595

⁴¹⁹ PPLP004128540

marketing messaging on the topic of the crush-resistant formulation of OxyContin introduced in 2010. Publicis was looking for data to support the claim that the reformulation was effective in reducing opioid use disorder. They just couldn't find it. The message would have to be carefully crafted, because Publicis couldn't find evidence to support their message: that the reformulation reduced abuse rates. As one Publicis employee described it, "Ugh...":

To: Bruce Rinderman[bruce.rinderman@razorfishhealth.com]
From: Christina Ceniza
Sent: Mon 5/4/2015 4:06:00 PM (UTC-04:00)
Subject: Re: Abuse rates

Ugh – no you're right. I was trying to figure out if maybe the % of OXC to overall illicit use of pain killers went down, but it didn't. Maybe we can set up some time with Linda to talk through possible angles since she did a lot of leg work on lit search? Even if we can't find the data, we can craft the message and tell the Brand team what we WANT to say and see if their Medical Services group can come up with anything to support it?

Christina Ceniza

Director | Account

christina.ceniza@razorfishhealth.com
P 212.771.5157 M 646.469.9673

RAZORFISH | HEALTH

99 Hudson Street
New York, NY 10013, USA
razorfishhealth.com

From: Bruce Rinderman <bruce.rinderman@razorfishhealth.com>
Date: Monday, May 4, 2015 at 3:57 PM
To: Christina Ceniza <christina.ceniza@razorfishhealth.com>
Subject: Re: Abuse rates

Hi Christina,
Am I missing something or is there no story here? Please take a look at my markups (attached) and let's chat when you have a sec.
Thanks,
Bruce.

Bruce Rinderman

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4. Responding to an External Threat: The Centers for Disease Control

1 609. In response to the growing crisis, in March 2016 the Centers for Disease Control
2 and Prevention issued a *Guideline for Prescribing Opioids for Chronic Pain* (the “CDC
3 Guidelines”) in order to reduce the recognized overprescribing of opioids and the concomitant rise
4 in opioid use disorder.

5 610. Within a month of their issuance, Publicis provided an assessment of the threats and
6 opportunities that each of the twelve Guidelines posed. The “threat” was that the Guidelines would
7 result in reduced OxyContin prescribing. The “opportunity” was that the Guidelines could be used
8 to position Purdue’s products to sell *more* of them by *using* the Guidelines.

9 611. In general, the Guidelines were seen as a threat as they recommended actions that
10 ran directly counter to Purdue’s marketing efforts. For instance, the Guidelines recommended that
11 prescribers use the “lowest effective dosage” when prescribing opioids, which is anathema to the
12 titration and length of therapy messaging that Publicis and Purdue had been articulating and
13 delivering for years.

14 612. The Guidelines also called for a curtailment of prescriptions exceeding 90 morphine
15 milligram equivalents per day. These high dose prescriptions accounted for nearly half of total
16 OxyContin prescriptions and were each more profitable than their lower dosage equivalents. The
17 Guidelines therefore risked to substantially erode OxyContin revenue. Purdue estimated the cost to
18 Purdue resulting from implementation of the Guidelines could be in excess of twenty million dollars
19 annually in lost sales in single state.
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26 **iii. Unbranded Marketing**
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613. It might be obvious, but “unbranded” opioid marketing does not promote any particular brand of opioid. Instead, unbranded marketing promotes opioids as a *class* of drugs worthy of ever increased prescription. Here, Publicis excelled in its work for Purdue.

614. If one thinks of the entire opioid market as a pie, each individual brand (as well as generic formulations) would comprise individual slices. Crucially, *even if* an individual product’s market share does not change, that portion can grow in value if the *overall* market grows. The larger the pie, the larger the slice.

615. The long-term goal was to “make the whole pie bigger, not only for us, but for our competitors as well,” a Purdue executive explained in a 2000 speech.⁴²⁰

1. Practical Tools to Advocate for yourself.

616. On January 22, 2012, Jennifer Grey, the actor known for co-starring in “Dirty Dancing,” appeared as a “patient advocate” on a local television talk show in San Francisco to discuss “Partners Against Pain,” a campaign with which she was affiliated. Noting the website’s address for the audience, she explained, “it’s called PartnersAgainstPain.com, and it’s a really interesting educational program... It’s a campaign that was meant to help people become advocates for themselves who are in chronic pain and because chronic pain is such an insidious syndrome.”⁴²¹

⁴²⁰ Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, “Inside the opioid industry’s marketing machine,” *Washington Post*, December 6, 2019, *available at*: <https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/>

⁴²¹ Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, “Inside the opioid industry’s marketing machine,” *Washington Post*, December 6, 2019, *available at*: <https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/>



617. In 2019, Grey provided the *Washington Post* with the following statement regarding her prior affiliation with PAP⁴²²:

When this unbranded [Purdue] Pharma campaign was brought to me in 2011, I was excited by the opportunity to help people who, like myself, suffered from chronic pain by giving them practical tools to advocate for themselves and manage their pain in a safe, responsible way. **I never suspected I was being used to potentially advance a darker agenda.** (emphasis added).

618. Rosetta and Purdue designed the PAP campaign together. [REDACTED]

[REDACTED] They were the ones who “brought” the “unbranded [Purdue] Pharma campaign” to Grey.

619. From the outset, [REDACTED]

[REDACTED] 424 [REDACTED]

⁴²² Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, “Inside the opioid industry’s marketing machine,” *Washington Post*, December 6, 2019, available at: <https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/>

⁴²³ PPLP003518651

⁴²⁴ PPLP003518651

1 [REDACTED]
 2 [REDACTED]
 3 620. PAP was part of Purdue's broader efforts in the realm of "Patient Access," or, put
 4 differently, efforts to ensure that OxyContin was well-known and easily available to patients who
 5 desired to advocate for themselves and ask their doctor about OxyContin.⁴²⁷ One method was to
 6 emphasize that pain is under-treated. [REDACTED]
 7 [REDACTED]
 8 [REDACTED]
 9 [REDACTED]
 10 [REDACTED]

11 621. Ms. Grey's later concern that she was "used to potentially advance some darker
 12 agenda" was prescient. There was more to it than "providing practical tools" to the local television
 13 audience so that they could "advocate" for themselves.
 14

15 622. [REDACTED]
 16 [REDACTED]
 17 [REDACTED]
 18 [REDACTED]⁴³⁰ In furtherance
 19 of that goal, [REDACTED]
 20 [REDACTED]
 21 [REDACTED]
 22 [REDACTED]

23
 24 ⁴²⁵ PPLPC012000409258

25 ⁴²⁶ PPLPC017000301209

26 ⁴²⁷ See Dr. Anna Lembke, *Drug Dealer, M.D.*, pg. 58 (noting that the common pharmaceutical refrain to "Ask your
 27 doctor if drug X is right for you" – a form of patients advocating for themselves in conversations with healthcare
 28 providers – "can influence prescribing because doctors are eager to please their patients, and when a patient asks about
 a particular medication, a doctor may prescribe it over other comparable choices.").

⁴²⁸ PPLPC017000541631

⁴²⁹ PPLPC017000328575, at 328587. [REDACTED]

⁴³⁰ PPLPC017000328575, at 328586.

1 [REDACTED]
2 (emphasis added).

3 623. In other words, Grey was hired to sell more drugs. Her work was just another line
4 item in the marketing budget, and Rosetta and Purdue expected a return on the money spent for it.
5

6 624. Not content with Grey alone, Rosetta and Purdue enlisted Country Music Icon
7 Naomi Judd as well. “Judd wants people to know the journey to appropriate pain management can
8 begin with a visit to the recently updated Partners Against Pain website
9 (www.PartnersAgainstPain.com),” proclaimed the press release.⁴³² [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]

27 625. Like Grey, Judd appeared in television spots as a “patient advocate”.⁴³⁴
28 [REDACTED]

⁴³¹ PPLPC017000328575, at 328587.

⁴³² See <https://ftper.newsusa.com/Pdfs/NaomiJudd.pdf>

⁴³³ PPLP003518651 at 3518686 (underlined emphasis in original; italicized emphasis added) [REDACTED]
[REDACTED]

⁴³⁴ See <https://www.youtube.com/watch?v=cUav8M9mep4>



626. “From day to day, pain can limit your ability to work, your hobbies, even the simple joys of huggin’ somebody you love,” she explained.⁴³⁵

627. Five years later, in 2016, Publicis proposed to revamp the *Partners Against Pain* website in light of the fact that the website had been “named in lawsuits.” Better to “start from scratch,” Publicis proposed. Publicis instead pitched to Purdue its “Patient Support Program.” The ultimate goal of the new campaign would be the same as the original *Partners Against Pain* campaign, “extending patients’ length of therapy.”

2. Join the Team!

628. Razorfish Health was the agency of record for Purdue in connection with the launch of the now-defunct website TeamAgainstOpioidAbuse.com.⁴³⁶ Purdue claimed the website was

⁴³⁵ See <https://www.youtube.com/watch?v=cUav8M9mep4>

⁴³⁶ Kevin McCaffrey, “Purdue debuts opioid-abuse resource,” Medical Marketing and Media, August 17, 2015m, available at: <https://www.mmm-online.com/home/channel/campaigns/purdue-debuts-opioid-abuse-resource/>

1 “designed to help healthcare professionals and laypeople alike learn about different abuse-deterrent
2 technologies and how they can help in the reduction of misuse and abuse of opioids.”⁴³⁷

3 629. The unbranded website contained misleading information regarding the
4 effectiveness of abuse-deterrent properties of certain opioid formulations, including Purdue’s
5 reformulated OxyContin and Hysinglia. At the time, only three abuse-deterrent formulations were
6 available on the market (the third was Embeda, manufactured by Pfizer).⁴³⁸ “The concept is that
7 we’re all part of a team,” explained Dr. David Haddox, Purdue’s Vice President of Health Policy.⁴³⁹

9 3. The Meaning of the Message

10 630. There was a recursive nature to the marketing of opioids as companies evolved from
11 *growing* the market for opioids to *responding* to the abuse and dependency issues that were the
12 natural outgrowth of that initial boom in opioid sales. “Hello, my name is Mark Timney... We at
13 Purdue are committed to doing everything we can to reverse this public health problem,” read the
14 script written by Rosetta for newly-installed Purdue CEO Mark Timney to read on a 60-second
15 television ad prepared by Rosetta in 2014.

17 631. Initially, opioids were marketed primarily based on their efficacy (while
18 disregarding their abuse liability). The PAP campaign was one facet of that effort. Once abuse
19 became a concern, opioid marketers then sought to contextualize opioid addiction within a broader
20 context of the individuals’ right to manage their own pain as a part of their own interactions with
21 the nation’s healthcare system. The words Timney said on TV and the website
22 TeamAgainstOpioidAbuse.com exemplify this later approach.

26 ⁴³⁷ “Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com,” Purdue, Aug. 17, 2015,
27 <http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/>.

28 ⁴³⁸ Kevin McCaffrey, “Purdue debuts opioid-abuse resource,” Medical Marketing and Media, August 17, 2015m,
available at: <https://www.mmm-online.com/home/channel/campaigns/purdue-debuts-opioid-abuse-resource/>

⁴³⁹ *Id.*

632. Melina Sherman, of the Institute for Public Knowledge at New York University, has written extensively regarding the evolving communications strategies used to market opioids. She explained, “[a]s its name indicates, the *Team Against Opioid Abuse* website is discursively constructed around the theme of abuse prevention – a decision that works strategically to shield the company [Purdue] from the negative press and attention being directed at its products.”⁴⁴⁰ But while the website did not specifically name brands of abuse-deterrent opioids, the website nonetheless operated to promote further use of Purdue’s drugs. Of the three abuse-deterrent opioid products then on the market, Purdue manufactured two of them. As such, “the site also functioned as a marketing platform for those same drugs, which it framed as a solution to the problem of opioid addiction and abuse.”⁴⁴¹

633. It is no accident that Ms. Grey spoke about providing “practical tools” to *consumers* in order to allow them to “advocate” for themselves. These tactics, subtle and insidious as they are, are meant to increase overall opioid prescribing. “Pharmaceutical companies often mobilize education campaigns around a particular diagnosis in order to indirectly market the cure and as a mean of evading legal constraints that restrict the ways that companies advertise their drugs to consumers.”⁴⁴²

634. Ms. Grey expressed concern about being used for a “darker agenda.” It was simply to sell more drugs.

635. For example, the *Partners Against Pain* website that Ms. Grey promoted “groomed” potential opioid customers by offering assessment tools to website visitors – including “checklists and lists of questions used to guide patients through the process of obtaining medication from their

⁴⁴⁰ Melina Sherman, “How to Train Your Opioid Consumer,” *Communication, Culture & Critique* Vol. 10 (2017), Pgs. 600-601.

⁴⁴¹ *Id.*

⁴⁴² Melina Sherman, “How to Train Your Opioid Consumer,” *Communication, Culture & Critique* Vol. 10 (2017), Pg. 599 (citing Angell, M. (2004). *The truth about drug companies: How they deceive us and what to do about it*. New York, NY: Random House).

doctors,” as a means of educating the viewer.⁴⁴³ The website also included a “Find a Doctor” tool, whereby viewers could search for pain management practitioners in their local area.

636. As the Rosetta ad that Purdue CEO Mark Timney read on TV emphasized, “Purdue is greatly expanding our ongoing efforts to help educate the public about prescription opioid abuse. We will be doubling our investment in 2015 to continue building awareness about the problem and better educating physicians, pharmacists, school health officials, insurers, and lawmakers about the risks of opioid abuse.” TeamAgainstOpioidAbuse.com was one such educational effort.⁴⁴⁴

637. But “tools such as these go further than education: They also function as technologies of power that manage communication and information in a way that is normative and directional and, in so doing, guide visitors’ behavior toward actions that benefit the company.”⁴⁴⁵

638. Dr. Marcia Angell, former Editor in Chief of the *New England Journal of Medicine*, summed things up plainly:⁴⁴⁶

No one should rely on a business for impartial evaluation of a product it sells. Yet the pharmaceutical industry contends it educates the medical profession and the public about its drugs and the conditions they treat, and many doctors and medical institutions – all recipients of the industry’s largesse – pretend to believe it. So does the government. But “education” comes out of the drug companies’ marketing budgets. That should tell you what is really going on.

639. Publicis employee Karl Tiedemann summed it up tidily, stating that the work Publicis was doing for Purdue was “not about education, but persuasion.”

⁴⁴³ Melina Sherman, “How to Train Your Opioid Consumer,” *Communication, Culture & Critique* Vol. 10 (2017), Pg. 599.

⁴⁴⁴ Even today, these educational efforts are cited as justification for Purdue’s actions. See Eric Russell, “Portrayed as villain in TV series about opioid crisis, ex-U.S. attorney for Maine says he didn’t sell out,” Portland Press Herald, February 27, 2022, available at: <https://www.pressherald.com/2022/02/27/portrayed-as-villain-in-tv-series-about-opioid-crisis-ex-u-s-attorney-for-maine-says-he-didnt-sell-out/> (“McCloskey said the scene depicts an inaccurate timeline and he was especially disappointed with the insinuation that he was paid by Purdue to keep quiet. ‘There’s no truth to that whatsoever,’ he said. ‘Purdue did a number of things I asked them to do. They took a pill off the market because I asked them to do it. They worked on tamper-proof prescription pads. They spent millions producing educational brochures.’”) (emphasis added).

⁴⁴⁵ Melina Sherman, “How to Train Your Opioid Consumer,” *Communication, Culture & Critique* Vol. 10 (2017), Pg. 599.

⁴⁴⁶ Dr. Marcia Angell, *The Truth About the Drug Companies*, Random House, 2004, Pg. 135.

640. A 2015 Publicis presentation backed up Tiedemann's statement. It identified "patient education" and "increase[ing] awareness as the "strategies" to achieve the "objectives" of "grow[ing] volume" in light of, among other things, "increasing pressure to reduce abuse, diversion, and overdose:"

2015 OxyContin Strategic Imperatives Updated 7/10		
Opportunity/Issue	Objective	Strategy
<ul style="list-style-type: none"> No IROs have ADPs Likely national up-scheduling of hydrocodone Segmented messaging with a promotionally-sensitive brand Little approvable branded messaging to drive IRO-to-ERO conversion Continued declining mean patient dose Patient understanding of chronic pain management 	Grow volume/ slow erosion	Increase conversions from oxycodone IROs by educating HCPs on how to identify appropriate patients
		Drive appropriate titration through ongoing reassessments and patient education
<ul style="list-style-type: none"> Increasing pressure to reduce abuse, diversion and overdose Limited prescriber understanding of current OxyContin ADP evidence Potential Tier 4 approval Potential approval of new ER oxycodones with ADPs OxyContin has 7 tablet strengths Continued pharmacist role in opioid Rx vetting 	Increase choice of OxyContin as 1 st branded ERO through meaningful differentiation	Increase awareness, understanding and relevance of OxyContin abuse deterrent properties to drive preference vs. all other opioids
		Maintain payer coverage; maximize pull-through opportunities and patient affordability

641. Moreover, unbranded marketing schemes like the one in which Ms. Grey unwittingly participated have a broader purpose of creating an information ecosystem designed to benefit the interests of pharmaceutical companies. As Verilogue noted, by "shaping the dialogue," one can "shape the future."⁴⁴⁷

642. Dr. Sherman explained,

This practice of dispersing branding materials in new contexts is emblematic of what Dumit (2012) has referred to as "strategic ubiquity," a tactic in which companies attempt to create a "universe" of syndicated and sponsored content through forming alliances with advocacy groups and developing partnerships with other influential third parties. For potential customers navigating this landscape, *every piece of*

⁴⁴⁷ See *infra*, fn. 493 and accompanying text.

information they read or hear about inevitably directs them toward specific actions that will serve the benefit of the company.⁴⁴⁸

643. The strategic intent of these campaigns, then, is “to construct an echo-chamber of pro-opioid information.”⁴⁴⁹

644. One example of this echo-chamber is Publicis’ groundbreaking work with regulators on their own opioid marketing campaigns. In 2018, Razorfish Health partnered with the FDA’s Center for Drug Evaluation and Research (CDER) to design the “Search and Rescue” campaign, which “makes innovative use of optimized search and direct email to reach family physicians, physician assistants and nurse practitioners, and in states with the highest opioid prescribing rates.”⁴⁵⁰ Razorfish’s campaign for the FDA was designed to further the same educational messages Purdue was espousing, to “equip prescribers to be proactive in identifying and helping patients at risk for prescription drug abuse.”⁴⁵¹

645. In other words, Publicis was able to deliver Purdue messages through alternative channels, including not only unbranded websites, but through the mouthpiece of *Purdue’s regulator*, the United States Food and Drug Administration, as well. *That* is an echo-chamber.

iv. Qui audet adipiscitur

646. “By nature, healthcare advertising provides a crutch to advertisers and marketers in the form of industry guidelines and regulations. We’re quick to point out why we *can’t* do

⁴⁴⁸ Melina Sherman, “How to Train Your Opioid Consumer,” *Communication, Culture & Critique* Vol. 10 (2017), Pg. 603. (citing Dumit, J. *Drugs for life: How pharmaceutical companies define our health*. Durham, NC: Duke University Press) (emphasis added).

⁴⁴⁹ Melina Sherman, “Opiates for the masses: constructing a market for prescription (pain)killers,” *Journal of Cultural Economy*, Vol. 10, Issue 6, 2017, available at: <https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010>

⁴⁵⁰ See <https://drugfree.org/newsroom/news-item/partnership-drug-free-kids-announces-relaunch-search-rescue-opioid-prescriber-education-campaign-website/>

⁴⁵¹ *Id.*

something, rather than eager to question how we could make something work within those boundaries,” pronounced Publicis Health Media’s Media Director, Eric Delash.⁴⁵²

647. Instead, Delash encouraged pharmaceutical marketers to “embrace risk.”⁴⁵³

Challenge the status quo. Disrupt the norm. Create your Gritty. Embrace strategic risk and drive real innovation in healthcare marketing.

648. Delash’s dashing attitude is reminiscent of prior rakish campaigners. “Who dares wins,” chose Sir David Stirling before him.⁴⁵⁴ Naturally, Publicis has long embodied the principles espoused in its Media Director’s blog post. Indeed, Publicis has embraced risk and dared greatly⁴⁵⁵ on behalf of its clients. In 2016, Publicis submitted proposed work for the aforementioned TeamAgainstOpioidAbuse.com website, as well as a separate campaign for Hysinglia that it had pitched to Purdue, for consideration in the category of “Most Daring Campaign” in Medical Marketing and Media’s annual industry awards.⁴⁵⁶

v. Coda Part II

649. Success is determined by what is being measured. In one sense, Purdue was an inordinately profitable account for Purdue. Publicis’ relationship grew from its start in 2010 to

⁴⁵² Eric Delash, *Healthcare Marketers Must Embrace Risk to Innovate*, Publicis Health Media Blog, December 13, 2018, available at: <https://www.publicishealthmedia.com/perspective/healthcare-innovations/>

⁴⁵³ Eric Delash, *Healthcare Marketers Must Embrace Risk to Innovate*, Publicis Health Media Blog, December 13, 2018, available at: <https://www.publicishealthmedia.com/perspective/healthcare-innovations/>

⁴⁵⁴ See David Stirling: The Phantom Major, *National Army Museum*, available at: <https://www.nam.ac.uk/explore/david-stirling> (recounting the origin of the motto of the British Special Air Service – *Qui audet adipiscitur* – during World War II); see also: https://en.wikipedia.org/wiki/Who_Dares_Wins

⁴⁵⁵ See another rakish campaigner, Theodore Roosevelt, *supra*, fn 16. (“It is not the critic who counts; not the man who points out how the strong man stumbles or where the doer of deeds could have done them better. The credit belongs to the man who is actually in the arena, whose face is marred by dust and sweat and blood; who strives valiantly; who errs, who comes short again and again, because there is no effort without error and shortcoming; but who does actually strive to do the deeds; who knows the great enthusiasms, the great devotions; who spends himself in a worthy cause; who at the best knows in the end the triumph of high achievement, and who at the worst, if he fails, at least fails while **daring greatly**, so that his place shall never be with those cold and timid souls who neither know victory nor defeat.”)(emphasis added).

⁴⁵⁶ Incredibly, that year, “MM&M’s esteemed and independent panel of judges elected not to award a Gold for Most Daring Campaign... While some excellent and creative unsold work was entered, the judges felt that none of the submissions were precisely ‘daring’ enough, according to the judging criteria, to receive the top honor.” Tanya Lewis, *Most Daring Campaign of 2016*, Medical Marketing and Media, October 6, 2016, available at: <https://www.mmm-online.com/mmm-awards/most-daring-campaign-of-2016/> Not *all* who dare, win.

1 encompass practically all branded marketing business from Purdue six years later. By 2016,
2 Publicis was the agency of record for OxyContin, Butrans, Hysinglia, and Targiniq. “The growth
3 we continue to see in this business is phenomenal,” congratulated a Publicis group president to the
4 Purdue team. On March 22, 2016, John Dwyer emailed Karl Tiedemann to let him know that the
5 expected annual revenue from Purdue for that year was approximately \$12 million. “Oh boy,”
6 replied Tiedemann. The Subject line of the email thread was “We’re gonna need a bigger boat.” In
7 that sense, Publicis was very successful.

9 650. Viewed differently, Publicis’ daring work was outrageously successful for Purdue
10 and, more to the point, the Sacklers. After 2013, the goal of *E2E* was to [REDACTED]
11 [REDACTED] and this Publicis did with great success. The Sackler Strategy that Publicis sold yielded
12 large amounts of money available for distribution from Purdue to the Sackler family for over a
13 decade. In that sense, Publicis was very successful.

15 651. In another sense, Purdue itself ended up bankrupt and, just like its parent, the Purdue
16 Frederick Co., before it, a convicted felon. This might be something other than success.

18 652. On October 20, 2020, Purdue—Publicis’s co-conspirator—agreed with the United
19 States Department of Justice to plead guilty to improper marketing of OxyContin and other opioids
20 again (the “2020 Settlement Agreement”). This time the plea agreement concerned conduct from
21 2010 to 2018. The agreement includes \$8.3 billion in penalties from Purdue and \$225 million from
22 the Sackler family.

24 653. Purdue pled guilty to a dual-object conspiracy to defraud the United States and to
25 violate the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 353, violating anti-kickback laws,
26 and “using aggressive marketing tactics to convince doctors to unnecessarily prescribe opioids —
27
28

⁴⁵⁷ PPLPC018000873870.

1 frivolous prescriptions that experts say helped fuel a drug addiction crisis that has ravaged America
 2 for decades.”

3 654. The new plea agreement did not identify Purdue’s co-conspirators, but Purdue’s new
 4 guilty plea concerned Covered Conduct (as defined in the plea agreement) that directly implicates
 5 Publicis in the conspiracy, including the same conduct described in this Complaint.
 6

7 **m. Publicis and Other Opioid Manufacturers**

8 655. Publicis’ role in the propagation of the opioid epidemic extends far beyond its work
 9 with felons. During the pendency of its long-term relationship with Purdue, and their joint efforts
 10 to grow the *overall* opioid market, Publicis also partnered with Endo, Teva, Janssen, and others to
 11 market those clients’ opioid brands. While it sought to grow the overall pie, Publicis also
 12 endeavored to grow each slice. It attacked the problem from both angles. And in doing so, it
 13 deployed many of the same tactics, at the same time, for numerous competing opioid brands. If
 14 some of the following paragraphs appear redundant, there is a reason. Lots of manufacturers’ opioid
 15 marketing strategies looked a lot alike. Publicis was a common denominator.
 16

17 **i. Endo**

18 656. Publicis’ Saatchi and Saatchi unit (“Saatchi”) was the Agency of Record for Opana,
 19 Endo Pharmaceutical’s branded oxymorphone product. As described above, Opana is the same
 20 molecule as Endo’s previous product – Numorphan – depicted in the film *Drugstore Cowboy*.
 21

22 657. With the launch of Opana, Endo decided it was time for history to repeat itself. After
 23 Opana’s approval in 2006, Endo solidified its position as a pain specialist among manufacturers.
 24 By 2012, Endo’s opioid sales accounted for approximately \$403 million of its \$3 billion in revenue,
 25 more than 10% of its total sales. From 2010 to 2013, total Opana ER revenue alone exceeded \$1.1
 26 billion.
 27
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658. Opana and Numorphan were both oxymorphone. The brand name was the only thing that changed.⁴⁵⁸ What Endo removed from the market in 1979 due to abuse concerns, it re-introduced 27 years later. After 2006, Opana was on occasion referred to as “blue heaven,” or, more to the point, “new blues.”⁴⁵⁹

659. In 2017, Endo would once again remove its branded oxymorphone product from the market, and for the same reason. Endo’s abuse-deterrent formulation of Opana was removed at the request of the FDA due to acute concerns about its abuse potential.

1. Championing the Molecule

660. Publicis touted its new work for Endo Pharmaceuticals as one of its “main wins” of new business in 2018.⁴⁶⁰ But Publicis’ relationship with Endo already dated back more than decade.

[REDACTED]

[REDACTED]

661. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁴⁶³

⁴⁵⁸ Literally, the only difference was the name. See ENDO_OPIOID_MDL-00863548 (“[REDACTED] (emphasis added)).

⁴⁵⁹ https://www.deadiversion.usdoj.gov/drug_chem_info/oxymorphone.pdf

⁴⁶⁰ See <https://www.publicisgroupe.com/en/news/press-releases/publicis-groupe-2018-annual-results>. Publicis also touted its work with co-Defendant Allscripts as a “main win.” *Id.*

⁴⁶¹ ENDO-OPIOID_MDL-02090726

⁴⁶² ENDO_FLAG-01075412

⁴⁶³ ENDO_OPIOID_DEPMAT-000068238, at 000068258.

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⁴⁶⁴ ENDO_OPIOID_DEPMAT-000068238, at 000068255, 00068256. [REDACTED]
[REDACTED]
[REDACTED] ENDO-CHI_LIT-00446003

⁴⁶⁵ ENDO_OPIOID_MDL-02017196.
⁴⁶⁶ ENDO_OPIOID_MDL-03656526

1 [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 [REDACTED]
 5 **2. “Durable Efficacy”**

6 665. With respect to 12-hour dosing, the Federal Trade Commission has observed,
 7 “Compared with immediate-release oxymorphone formulation, oxymorphone ER provides longer-
 8 lasting, 12-hour pain relief that allows the patient to take fewer pills each day.”⁴⁶⁸ The problem,
 9 however, is that “in order to reduce dose frequency, each long-acting opioid carries more active
 10 pharmaceutical ingredient than its short-acting counterpart. This makes long-acting opioids such as
 11 Opana ER subject to abuse; crushing and ingesting the pills immediately releases the larger amount
 12 of active ingredient into the bloodstream.”⁴⁶⁹

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 14 666. With respect to 12-hour dosing, [REDACTED]
 15 [REDACTED]
 16 [REDACTED]
 17 [REDACTED] Separately, [REDACTED]
 18 [REDACTED]
 19 [REDACTED]
 20 [REDACTED]
 21 [REDACTED] [REDACTED]
 22
 23
 24

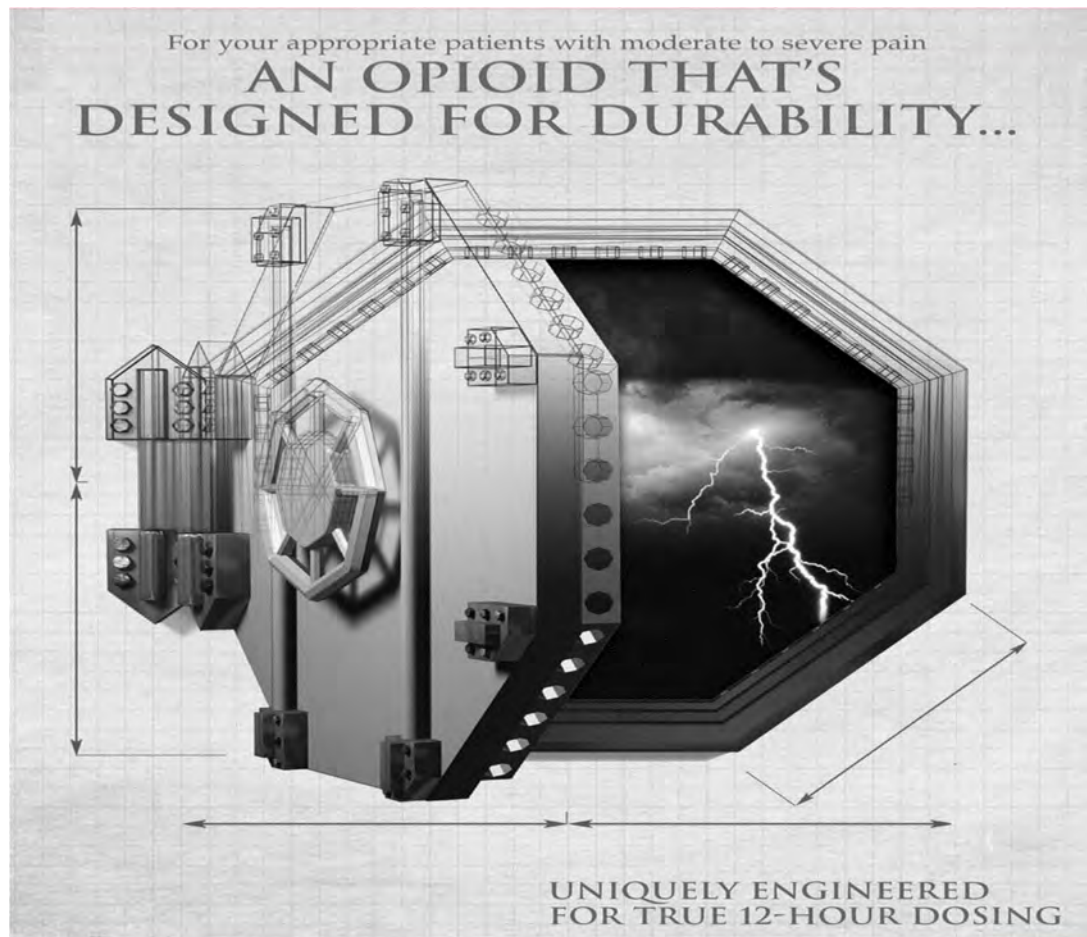
25 ⁴⁶⁷ ENDO_FLAG-01075147

26 ⁴⁶⁸ See Complaint, Federal Trade Commission v. Endo Pharmaceuticals, Inc. et al., No. 1:21-cv-217-RCL (D.D.C.) at
 Paragraph 57, *available* *at:*
https://www.ftc.gov/system/files/documents/cases/003_2021.03.02_revised_redacted_complaint.pdf

27 ⁴⁶⁹ See Complaint, Federal Trade Commission v. Endo Pharmaceuticals, Inc. et al., No. 1:21-cv-217-RCL (D.D.C.) at
 Paragraph 57, *available* *at:*
https://www.ftc.gov/system/files/documents/cases/003_2021.03.02_revised_redacted_complaint.pdf

28 ⁴⁷⁰ ENDO_FLAG-00911443

⁴⁷¹ ENDO_FLAG-01075147



3. Targeting Patients; Targeting Prescribers

667. The targeting work that Publicis's Rosetta performed for Purdue, described *supra.*, was done for other clients as well.

⁴⁷² ENDO_FLAG-00911567

⁴⁷³ ENDO_FLAG-00915025

1 [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 [REDACTED]
 5 [REDACTED]
 6 [REDACTED]
 7 [REDACTED]

8 668. Whether young or old, opioid naïve or an experienced user exhibiting signs of
 9 increasing opioid tolerance; or whether the pain was emanating from cancer or construction labor,

10 [REDACTED]

11 669. [REDACTED]

12 [REDACTED]

13 [REDACTED]
 14 [REDACTED] For example, [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED] Accordingly, [REDACTED]

20 [REDACTED]

21 [REDACTED]
 22 [REDACTED] 480

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26 ⁴⁷⁴ ENDO_FLAG-00915027

27 ⁴⁷⁵ ENDO_FLAG-00915029

28 ⁴⁷⁶ ENDO_FLAG-00915031

⁴⁷⁷ ENDO_FLAG-00915033

⁴⁷⁸ ENDO_OPIOID_MDL-02072698.

⁴⁷⁹ ENDO_OPIOID_MDL-02072698.

⁴⁸⁰ ENDO_OPIOID_MDL-02072698.

1 670. Also in 2007, [REDACTED]

2 [REDACTED]

3 Saatchi relied on the fact that the Joint Commission on Accreditation of Healthcare Organizations

4 (JCAHO) had recently adopted pain to as “the fifth vital sign,” and now required hospitals to assess

5 and treat patients’ pain as a matter of course.⁴⁸² JCAHO “mandated that hospitals poll each of their

6 patients at the end of their stay about whether their pain had been adequately treated.”⁴⁸³

7

8 671. The scores that the hospitals received were⁴⁸⁴ existentially important to the hospitals

9 seeking to maintain their accreditation. “A low score puts a hospital in jeopardy of being ruled

10 ineligible for Medicaid reimbursements.”⁴⁸⁵

11 672. [REDACTED]

12 [REDACTED]

13 [REDACTED]

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23 ⁴⁸¹ ENDO-NY_00625759.

24 ⁴⁸² Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, “Inside the opioid industry’s marketing machine,”

25 *Washington Post*, December 6, 2019, available at:

26 <https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/>

27 ⁴⁸³ Melina Sherman, “Opiates for the masses: constructing a market for prescription (pain)killers,” *Journal of Cultural*

28 *Economy*, Vol. 10, Issue 6, 2017, available at:

<https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010>

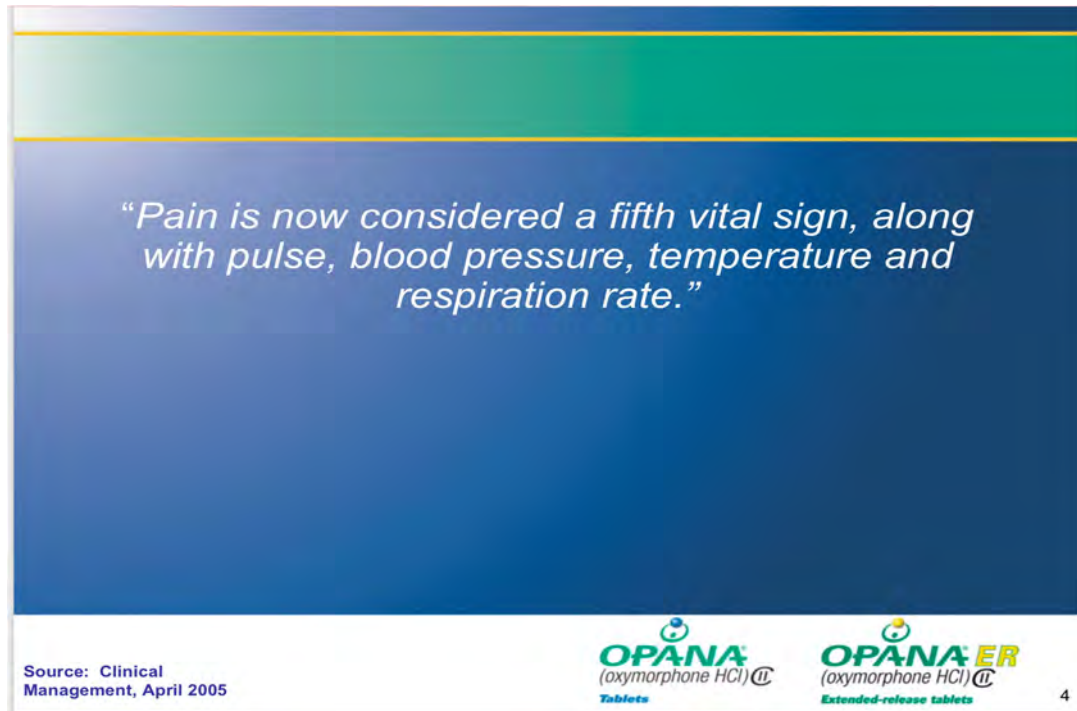
⁴⁸⁴ JCAHO has since abandoned the idea that pain is the fifth vital sign.

⁴⁸⁵ Melina Sherman, “Opiates for the masses: constructing a market for prescription (pain)killers,” *Journal of Cultural*

Economy, Vol. 10, Issue 6, 2017, available at:

<https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010>

⁴⁸⁶ ENDO-NY_00625759.



673. [REDACTED]

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674. The idea was simple: prescribe Opana, and you won't have to worry about low JCAHO scores. "It suffices to say that this system incentivizes the use of drugs – as reliable, fast-acting opioids for (temporarily) warding off the experience of pain. It is telling, after all, that the uptake of these new systems and instruments of objectively measuring the subjective experience of pain have paralleled steep increases in opioid prescriptions."⁴⁸⁸

⁴⁸⁷ ENDO-NY-00625759

⁴⁸⁸ Melina Sherman, "Opiates for the masses: constructing a market for prescription (pain)killers," *Journal of Cultural Economy*, Vol. 10, Issue 6, 2017, available at: <https://www.tandfonline.com/doi/full/10.1080/17530350.2017.1352010>

4. Beyond Saatchi: Endo's Broader Relationship with Publicis

675. Saatchi wasn't Publicis' only source of revenue from Endo. In January of 2012,

[REDACTED]

[REDACTED]⁴⁸⁹

676. A few months later, in April of 2012, Endo [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

677. Endo was keen on getting prescribers to switch from drugs like Vicodin to long acting opioids like Opana ER. [REDACTED]

[REDACTED]

[REDACTED] as well as [REDACTED]

[REDACTED]

[REDACTED]

ii. Teva

678. Teva Pharmaceuticals ("Teva") also availed itself of Publicis' myriad services. Teva sold Fentora, a fentanyl buccal tablet, after it acquired Cephalon, Inc. – Fentora's original

⁴⁸⁹ ENDO-OPIOID_MDL-03744169.

⁴⁹⁰ ENDO0111659

⁴⁹¹ ENDO0111708

⁴⁹² ENDO0111708

⁴⁹³ ENDO0111708

1 manufacturer – in 2011.⁴⁹⁴ The fentanyl pill was authorized by the FDA for use in the treatment of
 2 breakthrough pain in cancer patients receiving opioid treatment and who have become tolerant to
 3 it.⁴⁹⁵ By 2008, [REDACTED]
 4 [REDACTED]
 5 [REDACTED]
 6 [REDACTED]

7 679. From the outset, [REDACTED]
 8 [REDACTED]
 9 [REDACTED]
 10 [REDACTED]
 11 [REDACTED] Nonetheless, [REDACTED]
 12 [REDACTED]
 13 [REDACTED]
 14 [REDACTED]
 15 [REDACTED]⁴⁹⁹

16 680. [REDACTED]
 17 [REDACTED]
 18 [REDACTED]
 19 [REDACTED]
 20 [REDACTED]

21 681. By October 2009, [REDACTED]
 22 [REDACTED]
 23 [REDACTED]
 24 [REDACTED]

⁴⁹⁴ See <https://www.fiercepharma.com/pharma/teva-completes-acquisition-of-cephalon>

⁴⁹⁵ See <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fentanyl-buccal-tablets-marketed-fentora-information>

⁴⁹⁶ Publicis acquired Verilogue, which began as an independent company in 2006, in 2013. See <https://www.benzinga.com/pressreleases/13/12/tr4138223/publicis-groupe-acquisition-of-verilogue>

⁴⁹⁷ TEVA_MDL_A_01061669

⁴⁹⁸ TEVA_MDL_A_01061669 (emphasis in original)

⁴⁹⁹ TEVA_MDL_A_01061669

⁵⁰⁰ TEVA_MDL_A_01533872

1 [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 [REDACTED]
 5 [REDACTED]
 6 [REDACTED] Upon information
 7 and belief, [REDACTED] in this context refers to [REDACTED]
 8 [REDACTED]

9 682. Notably, [REDACTED]
 10 [REDACTED]
 11 [REDACTED]
 12 [REDACTED]
 13 [REDACTED]
 14 [REDACTED]
 15 [REDACTED]
 16 [REDACTED] Upon information and belief, [REDACTED]

17 [REDACTED]
 18 [REDACTED]
 19 683. The following year, [REDACTED]
 20 [REDACTED]
 21 [REDACTED]
 22 [REDACTED]
 23 [REDACTED]

25 _____
 26 ⁵⁰¹ TEVA_MDL_A_01091399

27 ⁵⁰² TEVA_CHI_00001592

28 ⁵⁰³ TEVA_CHI_00001592

⁵⁰⁴ TEVA_MDL_A_00721323 ([REDACTED])

⁵⁰⁵ TEVA_MDL_A_00721323

⁵⁰⁶ TEVA_MDL_A_02004878

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⁵⁰⁷ TEVA_MDL_A_02004912

⁵⁰⁸ TEVA_MDL_A_02769828

⁵⁰⁹ TEVA_MDL_A_08670617

⁵¹⁰ TEVA_MDL_A_02769830

⁵¹¹ TEVA_MDL_A_02769830. Subsys was a fentanyl spray product sold by competitor Insys Therapeutics. *See* “Founder and Former Chairman of the Board of Insys Therapeutics Sentenced to 66 Months in Prison,” Press Release, FDA, January 23, 2020, *available at*: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/founder-and-former-chairman-board-insys-therapeutics-sentenced-66-months-prison>

Publicis’ comprehensive and detailed knowledge of the market for fentanyl products extended to Lazanda, another fentanyl spray initially manufactured by Archimedes Pharma and subsequently purchased by Depomed, Inc. in 2013. Publicis Touchpoint Solutions was contracted to provide Depomed “15 full-time sales representatives employed by Publicis but dedicated to us” to market Lazanda. Form 10-Q, Depomed, Inc. dated August 8, 2013, at pg. 21.

⁵¹² TEVA_MDL_A_06478770. Lazanda is indicated for treatment in cancer patients. *See* https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022569s005lbl.pdf. TEVA_MDL_A_06478770.

1 686. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]⁵¹⁴

5

6 687. This [REDACTED] work was eerily similar to the work

7 Publicis performed for Purdue during the same time period in furtherance of *E2E*, as described

8 *supra*.

9 688. On March 3, 2014, [REDACTED]

10 [REDACTED] The following year, [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 689. As one Teva executive explained [REDACTED]

17 [REDACTED]

18 690. In November 2015, [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]⁵¹⁸ By the end of

22 the year, [REDACTED]

23 [REDACTED]

24

25 _____

26 ⁵¹³ TEVA_MDL_A_08670617

27 ⁵¹⁴ TEVA_MDL_A_08670617

28 ⁵¹⁵ TEVA_MDL_A_11132793

⁵¹⁶ TEVA_MDL_A_8649676

⁵¹⁷ TEVA_MDL_A_08650706

⁵¹⁸ TEVA_NY_00095129

⁵¹⁹ TEVA_MDL_SF_00044499

1 691. The Teva account was important to Publicis, and [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 692. A few months later, [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 **iii. Johnson & Johnson/Janssen**

14 693. Arista Marketing (hereinafter “Arista”) was a Publicis company eventually folded

15 in to Publicis Touchpoint Solutions. Arista specialized in “multi-channel physician access above

16 and beyond face-to-face detailing.”⁵²² “We create live conversations with physicians and other

17 healthcare professionals, ranging from 2-minute teledetails to 12-minute web-based video details,”

18 Arista explained.”⁵²³

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20 694. In 2009, [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

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25 ⁵²⁰ TEVA_MDL_A_08960291

26 ⁵²¹ TEVA_MDL_A_08734851

27 ⁵²² Publicis Strategic Solutions Group, “Arista Marketing Associates Rolls Out Multichannel Physician Access

28 Program for Leading Pharma Co.,” June 11, 2009, PRLOG, *available at*: <https://www.prlog.org/10256062-arista-marketing-associates-rolls-out-multichannel-physician-access-program-for-leading-pharma-co.html>

⁵²³ Publicis Strategic Solutions Group, “Arista Marketing Associates Rolls Out Multichannel Physician Access

Program for Leading Pharma Co.,” June 11, 2009, PRLOG, *available at*: <https://www.prlog.org/10256062-arista-marketing-associates-rolls-out-multichannel-physician-access-program-for-leading-pharma-co.html>

⁵²⁴ JAN-MD-00121873

1 695. Nucynta was Janssen’s branded tapentadol product. Nucynta was first approved as
 2 a Schedule II controlled opioid agonist tablet and oral solution in 2008 and indicated for “relief of
 3 moderate to severe acute pain in patients 18 years of age or older.”

4 696. [REDACTED]
 5 [REDACTED]
 6 [REDACTED]
 7 [REDACTED]
 8 [REDACTED]
 9 [REDACTED]

10 697. [REDACTED]
 11 [REDACTED]
 12 [REDACTED]
 13 [REDACTED]
 14 [REDACTED]
 15 [REDACTED]
 16 [REDACTED]⁵²⁷

17 698. [REDACTED]
 18 [REDACTED]

19 699. In 2010, [REDACTED]
 20 [REDACTED]
 21 [REDACTED]
 22 [REDACTED]
 23 [REDACTED]

24
 25 ⁵²⁵ JAN-MND-00106720

26 ⁵²⁶ JAN-MND-00106720

27 ⁵²⁷ JAN-MND-00106720

28 ⁵²⁸ TEVA MDL A 13645931 at pg. 11-12.

⁵²⁹ In 2011, Janssen obtained approval for a long-acting version Nucynta ER, which was indicated for “management of moderate to severe chronic pain in adults and neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults.”

⁵³⁰ JAN-MS-00018344 at 18368

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700.

701. Three years later,

Indeed, by 2013

while simultaneously working for competing products manufactured by others.

iv. Servicing Manufacturers in Groups

702. Publicis did more than perform discreet work for individual opioid manufacturers; it crafted industry-wide marketing efforts to boost sales not only of individual opioid products, but of opioids *generally*. A rising tide lifts all boats. Or, to borrow the Purdue’s executive’s analogy, Publicis worked to “make the pie bigger for all.”⁵³⁵

703. Accordingly, in addition to maintaining separate client relationships with multiple opioid manufacturers, Publicis also worked for industry-wide groups to coordinate marketing and advertising related to opioids, broadly.

⁵³¹ JAN-MS-00018344 at 18368

⁵³² JAN-MS-00772421 at 2, 5.

⁵³³ JAN-MS-00772421 at 6.

⁵³⁴ JAN_MS_01093081; JAN_MS_01093079

⁵³⁵ See *supra*. at Paragraph 90; Sari Horwitz, Scott Higham, Dalton Bennet and Meryl Kornfield, “Inside the opioid industry’s marketing machine,” *Washington Post*, December 6, 2019, available at: <https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/>

704. Likewise, [REDACTED]

v. Servicing Demand on the Comeback⁵³⁷ – Publicis and Orexo AB

705. The cognitive dissonance within Publicis as it embarked upon its work with Purdue on *E2E* must have been palpable. Three months after Publicis was working on OxyContin coupons, Swedish pharmaceutical company Orexo AB announced that the U.S. Food and Drug Administration had approved Zubsolv, its drug designed to treat opioid addiction. Zubsolv is a combination of buprenorphine and naloxone. At the time of Zubsolv's launch in 2013, Orexo projected peak sales of the drug to exceed \$500 million, annually.

706. But Orexo did not have a significant presence in North America when Zubsolv was approved. It did not have its own sales force in North America that could market its drug. As the most attractive market in which to sell opioid dependency treatments, Orexo desired to partner with someone who had the expertise and capacity to successfully launch Zubsolv in the United States.

707. On July 1, 2013, Orexo announced "that the company has entered into a commercial partnership with Publicis Touchpoint Solutions for the launch of Zubsolv in the United States...

⁵³⁶ JAN-NYDFS-0000123744

⁵³⁷ See Chris Rock, *Bigger & Blacker*, HBO TV Special, July 10, 1999, CR Enterprises, 3 Arts Entertainment, Production Partners, available at: https://www.youtube.com/watch?v=RRN3d5S_MTk ("There ain't no money in the cure; the money's in the medicine. That's how you get paid... on the comeback. That's how a drug dealer makes his money. On the comeback.")

Publicis Touchpoint Solutions will be responsible for the execution of all field-based promotion activities through dedicated sales representatives and medical support to health care practitioners through deployment of a dedicated medical scientific liaison team.”⁵³⁸

708. In announcing the partnership, Orexo Chief Executive Officer Nikolaj Sorensen emphasized Publicis’ “knowledge of the opioid dependence therapeutic area,” in addition to its expertise with “similar product launches,” as primary reasons Orexo chose Publicis to be its partner.

709. As described in detail above, Publicis did indeed have expertise with similar product launches. While its sales representatives in Publicis Touchpoint Solutions were diligently selling Zubsolv for Orexo, Publicis worked just as diligently through its other agencies with other opioid manufacturers to maximize the sales of the drugs that were the direct source of Zubsolv’s indication. The same year it partnered with Orexo to launch Zubsolv, Publicis billed Purdue Pharma around \$8mm for marketing work on OxyContin and other Purdue opioid products.

710. Most incredibly, Publicis began work on Purdue and McKinsey’s *E2E* project **less than three months** after its partnership with Orexo was announced.

711. Through its work with Orexo, Publicis gained knowledge of the market opportunities created by widespread opioid dependency, and of the co-dependence of the markets for opioid treatments and opioid use disorder treatments.

712. As Orexo, Publicis’ partner, described in its 2013 annual report, “[p]rescription painkillers containing opioids are highly addictive, and regular or long-term use can lead to physical dependence.” Orexo further observed that “[m]any abusers begin by taking opioids orally,” and that the misuse of opioid prescription drugs was a “growing problem,” with “opioid dependence more common than the abuse or, or dependence on, any other type of prescription medication.”

⁵³⁸ “Orexo Forms a Commercial Partnership with Publicis Touchpoint Solutions for Launch of Zubsolv in the US,” July 1, 2013, *available at*: <https://www.businesswire.com/news/home/20130701005515/en/Orexo-Forms-a-Commercial-Partnership-with-Publicis-Touchpoint-Solutions-for-launch-of-Zubsolv™-in-the-US>

713. Describing the addressable market for Zubsolv, Orexo stated that the “cost of prescription opioid abuse, dependence and misuses in the US is estimated to exceed USD 56 billion per year,” and further, “15,000 people die from opioid pain relievers each year in the US. Deaths from opioid pain relievers exceed those from all drugs and traffic accidents.”

714. The conclusion was obvious:

Zubsolv has entered a large and growing market. The current US market of products containing buprenorphine/naloxone amounts to approximately USD 1.9 billion, before rebates to payers, co-pay support and other discounts. The market continued to grow by 9 percent in value and 10 percent in volume during 2013. **Continued double-digit growth is likely in the years to come, and will be driven by the significant unmet medical need, the growing number of opioid dependent patients** as well as the impact of the Affordable Care Act.⁵³⁹

715. Publicis Touchpoint Solutions provided a contract sales force to Orexo through the second quarter of 2014, and continued to advise its client on Zubsolv sales through at least 2019.⁵⁴⁰

716. By 2015, Orexo stated flatly, “[t]here is no doubt opioid addiction has become one of the major health concerns in the US and a disease currently out of control.”⁵⁴¹ The market for Zubsolv was booming, with an 83% increase in revenue compared to the prior year.⁵⁴²

717. Throughout its time selling a treatment for opioid use disorder, Publicis endeavored on multiple fronts, with multiple clients, to maximize the sales of opioids, the drugs that cause the condition that Zubsolv – another drug it was paid to sell – treats. The synergies were hard to beat. Publicis helped Orexo service a demand it had a principal role in creating and sustaining through its *contemporaneous* work on E2E and other projects. Indeed, without Publicis efforts promoting opioids for its other clients, there may not have been an addressable market for Orexo’s product in the first place.

n. Alternative Channels: Publicis and Practice Fusion

⁵³⁹ See <http://mb.cision.com/Main/694/9557375/224609.pdf> (emphasis added).

⁵⁴⁰ See <https://www.linkedin.com/in/susan-broadnix-8794bb7/>

⁵⁴¹ See <https://mb.cision.com/Main/694/9942119/491960.pdf>

⁵⁴² *Id.*

1 718. In pharmaceutical sales, the traditional workhorse of sales and marketing campaigns
2 is the individual sales representative calling on individual prescribers to meet in-person with them
3 in order to extol the virtues of a given drug and encourage the doctor to prescribe more of it to
4 patients. Classically, this has been the primary channel through which a pharmaceutical company's
5 message has been delivered to the intended audience.
6

7 719. Of course, there are alternatives to face-to-face meetings with doctors by sales
8 representatives. In theory, wherever a prescriber's attention is focused at any given moment is a
9 potential spot to deliver content to her. Over the past few decades, for instance, doctors increasingly
10 interact with screens that they look at while at work. Forty years ago, doctors didn't walk around
11 their offices holding iPads, but they do now. This is an "alternative channel" through which a
12 message can be delivered, and Publicis endeavored with its clients to create multi-faceted
13 campaigns so that a prescriber would be surrounded, in effect, with pharmaceutical company
14 messaging coming from all directions: the people he has lunch with, the speakers at conferences he
15 attends, the ads on his screen, the search results on his computer when he uses Google to search for
16 a condition state, etc.
17

18 720. There are lots of alternative channels. [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
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⁵⁴³ PPLPC014000224450.

Channel	Potential Targets	Potential Tactics	Vendors	Cost	Impact
Associations	• Targets who are members	• Approved messaging; educational focus	• APS, AAPM, AAFP, ACP, AAOFP, AAPA, AAPM&R	Med	Med
EHR	• EHR-using targets	• POC messaging	• Practice Fusion	High	Med
			• AllScripts		
In-office	• High-value targets due to cost	• Customized wall charts	• McCallan Health	High	Med
			• Accent Health		
			• Media Health Network		
Surveys	• All targets	• ATU-style questions	• WorldOne Interactive	Low	Med
Nurse Focus	• All NP targets	• Same messaging as MD	• RNSights	Med	High
Pharmacist Focus	• All Pharmacy targets	• ADF/access messaging	• SK&A	Med	Med
MC Focus	• All MC targets	• ADF/access messaging	• SK&A	Med	Med
Contract Field Force	• IDNs	• Standard rep messaging	• Best MSLs	High	Med
Social	• All targets	• Educational messagings	• Doximity	Med	Med
			• QuantiaMD		
KOL Programs	• All targets	• KOL on-demand	• Synapse	High	Med
Conference Services	• Attendee lists	• High-value messaging	• Pain-related conferences	Med	High
Authenticated Website	• All targets	• High-value messaging	• UBM Medica	High	Med
eSample	• Sample-appropriate targets (Intermezzo)	• Sampling	• Physicians Interactive	High	Med
			• Doctor Directory		
Website	• All targets	• All messaging	• PurdueHCP.com	Med	High

ROSETTA

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721. These channels, when utilized together as part of an overall package, can be said to comprise the overall “marketing mix” that Publicis, ZS, McKinsey and others continually endeavor to optimize and espouse as a “best practice,” which is another way of saying that lots of the consultants’ other clients do the same thing. [REDACTED] Publicis stood athwart the industry, in a position to advise their clients on which vendors to pick to best utilize these alternative channels.⁵⁴⁴ In this way, as in others, it served as a hub, or an intermediary connecting multiple participants in the overall efforts to market opioids to maximum effect.

722. “EHR” stands for Electronic Health Record. It is a relatively new marketing channel, and one whose growth was spurred by federal legislation in 2009 that encouraged doctors to adopt electronic record-keeping methods for patient records. As early as 2012, Publicis was working with Purdue to develop banner advertising and other types of content that could be placed in the EHR

⁵⁴⁴ Indeed, this position athwart the distribution channels is what being an AOR is.

channel. This work continued at late as 2018, and Publicis, as AOR, also selected EHR vendors in which the content could be placed.

723. They chose Practice Fusion.

724. As the varieties of marketing channels above make clear, pharmaceutical marketing is complex. Publicis Health's Chief Digital Officer recently remarked on his complexity:

When we think about our ecosystem, the complexity goes beyond just regulatory. We are in a complex ecosystem in the sense that we are marketing to two different audiences in a patient, and a physician. We're hoping that they come together and have a productive conversation, and in that conversation, we're hoping that they talk about the treatment that we're marketing to them. And that's complex, I don't think there's any other industry that is met with that challenge.⁵⁴⁵

725. This complexity creates reams of data. ZS Associates, the pharmaceutical sales and marketing consultancy, has described the "endemic challenge" facing the pharma industry: "It has a complex and circuitous sales process involving drug manufacturers, physicians, pharmacies, patients, and insurance companies. Each step in a buying process creates data – and more of it is being created every day."⁵⁴⁶

i. Electronic Health Records – A New Frontier

726. These data streams may be used as a tool. The data available and the information provided by EHR is all-encompassing in its breadth. As ZS Associates noted, "[t]he spectrum of data is almost unprecedented: lab results, diagnoses, prescriptions, patient compliance, physician notes, and follow-on or replacement prescriptions."⁵⁴⁷ The result is that EHR data can provide an

⁵⁴⁵ Ray Rosti, Chief Digital Officer of Publicis Health Media, December 7, 2020, available at https://www.youtube.com/watch?v=AG4HLIDSQ_A

⁵⁴⁶ Steve Love, Sudhanshu Bhatnagar, Greg Rickman, and Jedy Wang, "The Value of EMR Data: Unlocking Insights That Drive Pharma Sales," *Journal of Pharmaceutical Management Science Association*, Spring 2016, available at: <https://library.net/document/zlewp5lq-value-emr-data-unlocking-insights-drive-pharma-sales.html>.

In 2011, ZS touted Publicis' endorsement of its own product offerings, such as Javelin. See <https://twitter.com/ZSAssociates/status/119892005756215297>

⁵⁴⁷ Steve Love, Sudhanshu Bhatnagar, Greg Rickman, and Jedy Wang, "The Value of EMR Data: Unlocking Insights That Drive Pharma Sales," *Journal of Pharmaceutical Management Science Association*, Spring 2016, available at: <https://library.net/document/zlewp5lq-value-emr-data-unlocking-insights-drive-pharma-sales.html>.

1 end-to-end perspective for the entirety of a patient’s journey from the diagnosis of a disease through
 2 treatment and through cure or death.⁵⁴⁸

3 727. This data can be used to sell more drugs. With the proliferation of electronic health
 4 data, vendors have arisen to aggregate and sell data sets and analytics platforms based on this data.
 5 These providers “now give pharma companies greater visibility than ever into its (*sic*) marketplace
 6 of buyers, consumers, and decision-makers – and the factors that drive sales.”⁵⁴⁹

8 **ii. What Practice Fusion does**

9 728. Practice Fusion was founded in 2005 as a vendor of free electronic health record
 10 storage (EHR) software. It “makes software that many doctors see on their devices. When you go
 11 into the exam room, your electronic records pop up on their screens.”⁵⁵⁰

12 729. Practice Fusion’s cloud-based EHR software platform serves tens of thousands of
 13 active health care providers in the United States, and the software is used during millions of
 14 physician-patient encounters each month. It is “the #1 cloud-based ambulatory EHR platform in
 15 the U.S.,⁵⁵¹ supporting 30,000 medical practices in delivering better care to 5 million patients a
 16 month. With a best-in-class satisfaction rate,⁵⁵² Practice Fusion is committed to delivering intuitive
 17 and easy-to-use health IT solutions to small, independent medical practices.”⁵⁵³

18 730. The business model was daring; most EHR vendors – Practice Fusion’s competitors
 19 – charge users to use their software platforms, typically in the form of a licensing fee. Practice
 20
 21
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25 ⁵⁴⁸ *Id.*

26 ⁵⁴⁹ *Id.*

27 ⁵⁵⁰ Brian Mann, “Health Care Software Firm Fined \$145M in Opioid Scheme With Drug Companies,” *NPR*, February
 1, 2020, available at: [https://www.npr.org/2020/02/01/801832788/healthcare-software-firm-fined-145m-in-opioid-](https://www.npr.org/2020/02/01/801832788/healthcare-software-firm-fined-145m-in-opioid-scheme-with-drug-companies)
[scheme-with-drug-companies](https://www.npr.org/2020/02/01/801832788/healthcare-software-firm-fined-145m-in-opioid-scheme-with-drug-companies)

28 ⁵⁵¹ SK&A, Report on Physician Office Usage of Electronic Healthcare Records Software (February 2016).

⁵⁵² Reaction Data, [Report on EHR Satisfaction According To Physicians](#) (January 2018).

⁵⁵³ Practice Fusion Company Profile, <https://www.practicefusion.com/about/>

1 Fusion was different. Ryan Howard, founder and CEO of Practice Fusion, explained, “our product
2 being free and web-based was incredibly unorthodox.”⁵⁵⁴

3 731. The company didn’t charge the doctors for these intuitive and easy-to-use health IT
4 solutions. It was free to them.⁵⁵⁵ Instead, Practice derived revenue from payments from
5 pharmaceutical companies in exchange for ad space, and other marketing products like “clinical
6 decisions alerts” (CDS) in its EHR software that served as advertisements for the pharmaceutical
7 company’s products.⁵⁵⁶

9 732. Practice Fusion marketed its platform to the pharmaceutical companies as a way to
10 influence prescriber behavior. For instance, Practice Fusion’s pitch materials to pharmaceutical
11 companies indicated that a pain CDS could be aligned with that company’s “brand objectives.”

12 733. From the advertiser’s perspective, this product offering was tantalizing. [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]

19 “Practice Fusion, the cloud-based
20 electronic medical system, mirrors the real-life workflow of a doctor’s office,” explained John
21 Mehta, Publicis Sapient’s Chief Experience Officer from 2019 to 2020.⁵⁵⁹

22 _____
23 ⁵⁵⁴ Ryan Howard, CEO Practice Fusion, *Cracking the Entrepreneur Code*, September 26, 2011, *available at*:
<https://www.youtube.com/watch?v=JaTIgMUEc9Y&t=1067s>

24 ⁵⁵⁵ “If something is free, you’re the product.” See Richard Serra, Carlota Fay Schoolman, *Television Delivers People*,
1973 (“The Product of Television, Commercial Television, is the Audience... Television delivers people to an
25 advertiser.”), *available at*: <https://www.youtube.com/watch?v=LvZYwaQIJsg>

26 ⁵⁵⁶ Christina Farr, “Practice Fusion, once headed for \$1.5 billion valuation, ends in ‘disappointing’ fire sale,” *CNBC*,
January 8, 2018, *available at*: [https://www.cnbc.com/2018/01/08/practice-fusion-acquired-by-allscripts-for-100-](https://www.cnbc.com/2018/01/08/practice-fusion-acquired-by-allscripts-for-100-million-in-cash.html)
27 [million-in-cash.html](https://www.cnbc.com/2018/01/08/practice-fusion-acquired-by-allscripts-for-100-million-in-cash.html) (“Rather than selling expensive licenses, the company makes money by showing ads to
28 physicians that use the service.”)

27 ⁵⁵⁷ See [REDACTED] TEVA_CHI_00437579.

28 ⁵⁵⁸ [REDACTED] TEVA_CHI_00437579.

⁵⁵⁹ John Maeda, “Better Health by Design: Making Healthcare Tech More Usable, Understandable And Profitable,”
TechCrunch, December 8, 2015, *available at*: <https://techcrunch.com/2015/12/08/better-health-by-design-making->

734. The brand objectives that Practice Fusion pursued for Purdue and other opioid manufacturers included expanding the market share of a given company's extended-release opioids *as well as* growing the *overall* size of the ERO opioid market by targeting "opioid naïve" patients and patients that were on immediate release ("IRO") opioid therapies.

735. Practice Fusion's EHR platform provided Purdue and other opioid manufacturers a way to reach into the examination room and interact with the prescriber and the patient by utilizing the "wealth of data" available in EHR records⁵⁶⁰ to deliver targeted messaging when and *when* it matters. Moreover, Practice Fusion provided its customers (pharmaceutical companies, not doctors) with "novel tools" to "drive appropriate care for patients with chronic pain," by utilizing private, individualized patient health care records in order to target the delivery of messages intended to increase overall ERO prescribing. The platform enabled Practice Fusion's customers to insert promotional messaging throughout the provider workflow, including during patient visits and "patient-centric provider targeting."⁵⁶¹ Practice Fusion provided these services to its customers so without patient or physician consent.⁵⁶²

736. As early as 2012, Publicis was working with Purdue to develop banner advertising and other types of content, including CDS alerts, that could be placed within the EHR channel. This work continued at late as 2018, and Publicis, as AOR, also selected EHR vendors in which the content could be placed: Practice Fusion.

[healthcare-tech-more-usable-understandable-and-profitable/](https://forward.recentprogress.it/en/magazine/number-17-places-of-care/articles/better-health-by-design/). See also <https://forward.recentprogress.it/en/magazine/number-17-places-of-care/articles/better-health-by-design/> (identifying Maehda as Publicis' Chief Experience Officer. According to LinkedIn, Maehda left Publicis Sapient in October of 2020. See <https://www.linkedin.com/in/johnmaeda/>).

⁵⁶⁰ See PFDPA00000025-27 (noting the wealth of data gleaned from access to the medical records helped build a franchise to treat patients in pain "around the clock" and expand the data sets of conditions for which to prescribe opioids).

⁵⁶¹ *Id.* at 4.

⁵⁶² Press Release, Department of Justice, Electronic Health Records Vendor to Pay \$145 Million to Resolve Criminal and Civil Investigations, Practice Fusion Inc. Admits to Kickback Scheme Aimed at Increasing Opioid Prescriptions (Jan. 27, 2020), <https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0>

1 **iii. Publicis and Practice Fusion**

2 737. Publicis piloted Practice Fusion to Purdue over years of working with both. In one
3 sense, this is Publicis performing its role as AOR for Purdue. The AOR not only *creates* the content,
4 but *places* it as well. The AOR acts as a distributor of the client's ads to people selling space in
5 which to put them. A billboard on the side of an interstate, a prospective patient's TV screen,
6 signage on the wall above the urinals in a barroom bathroom, a prescribers' iPad screen... it's all
7 placement. Choosing the best places and putting Purdue's messages in them was part of Publicis'
8 job as AOR.
9

10 738. One of the best spots, Publicis informed Purdue, was Practice Fusion. In the simplest
11 of terms, Practice Fusion had advertising space to sell in the form of banner advertising and
12 embedded features such as CDS alerts that could be placed within Practice Fusion's software
13 programs that prescribers looked at on their screens throughout the day, and Publicis put some
14 Purdue content there.
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16 739. In October 2013, [REDACTED]
17 [REDACTED]
18 [REDACTED] Practice Fusion's subsequent work with Purdue was
19 carried out in coordination and conjunction with Publicis, and as a part of the McKinsey's
20 implementation of *E2E* alongside Purdue to [REDACTED]
21

22 740. Publicis even paid Practice Fusion's invoices on behalf of Purdue.

23 741. Publicis and Practice Fusion coordinated their work for Purdue. In April 2014, with
24 *E2E* in full swing, Publicis' John Dwyer reached out to Practice Fusion's Jim Pantaleo to discuss
25 some "aggressive EMR strategies" for Purdue, and focused on the point of prescription, when the
26

27 ⁵⁶³ PPLPC014000224450; PPLPC014000224448 ([REDACTED])
28 [REDACTED]
PPLPC018000873870.

1 doctor is deciding whether and what to prescribe to a patient. For doctors contemplating prescribing
 2 an immediate-release opioid (IRO), an ad featuring Oxycontin's 12-hour dosing would appear. A
 3 doctor contemplating an extended-release opioid (ERO) would see an ad touting OxyContin's
 4 formulary coverage. Dwyer also suggested a "reassessment" reminder appear within the EMR each
 5 time a patient receives a consecutive prescription for OxyContin, in which the prescriber would be
 6 reminded of Purdue's titration messaging, described above. Dwyer suggested four such
 7 "aggressive" strategies, and suggested that the strategies that have the "highest ROI" and are the
 8 best "Rx drivers" be reinvested in:

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To: John Dwyer[john.dwyer@rosetta.com]
 From: Jim Pantaleo
 Sent: Mon 8/11/2014 9:49:51 AM (UTC-04:00)
 Subject: RE: Purdue Brands - EMR Strategy/Ideas/Discussion

Thanks John. Checking in sounds like a good plan.

In the meantime, I will put together messaging examples of how others are targeting in the platform and send to you.

We may not have the exact strategic messaging tactics, but I believe all of the below can be executed.

I'll send by end of day; first thing tomorrow.

Jim

From: John Dwyer [mailto:john.dwyer@rosetta.com]

Sent: Monday, August 11, 2014 9:36 AM

To: Jim Pantaleo

Subject: Re: Purdue Brands - EMR Strategy/Ideas/Discussion

Hi Jim,

I agree, and I think we should try to check in with each other for a few minutes every other week or so while these programs are of high interest to Purdue.

Here are the 4 approaches we discussed on Friday's meeting. Again, with these approaches, the most helpful thing you can provide would be examples of other products that have used a targeting strategy to serve ads based on competitor brands or generics in the same category.

EMRs for EROs (addresses Conversion, Titration, opioids with abuse-deterrent properties (OADPs), Mgd Care)

- Pilot 3 aggressive EMR strategies in Q1 and quickly optimize and reinvest in the 1-2 highest ROI and Rx drivers

1. Target IRO oxycodone Rx's with branded OxyContin Q12h msg or unbranded ER teaser msg
2. Serve a "Reassessment" reminder msg each time pt receives consecutive OxyContin Rx
3. Target non-ADP Rx's with branded OxyContin ADP msg or unbranded ADP teaser msg
4. Target ERO Rx's with OxyContin MC coverage message or unbranded coverage teaser msg

Thanks again for coming by on Friday and sharing so much information.

John Dwyer

Associate Partner, Healthcare

O: 212 771-5109 M: 917 797-9317

99 Hudson St. 7th Fl New York, NY 10013 USA

Rosetta.com

742. Three months later, in July 2014, Publicis proposed that EHR channels be used to encourage conversion of immediate-release opioids (IRO) patients to extended-release opioids (EROs). This would have the effect of growing the overall size of the ERO market by creating new

1 ERO users who previously were prescribed IROs. One idea was to target any patient who has been
 2 prescribed an IRO “multiple times (3 or 4) with a branded or unbranded message for OXC.”

3 743. Consistent with the overall goals of *E2E*, Publicis encouraged Practice Fusion to
 4 help grow the ERO market by encouraging conversions of IRO users. Publicis informed Purdue
 5 that Practice Fusion had the relevant capabilities: the ability to deliver “Branded OxyContin &
 6 clinical messages... during patient eRx, patient Medication Selection... and edit patient
 7 Medication.” Publicis’ John Dwyer asked his colleagues whether Practice Fusion had “any kind of
 8 ROI or Rx impact metrics around these that they can share?”

10 **iv. Practice Fusion and Purdue**

11 744. In April of 2013, Publicis agreed to Purdue place banner advertisements inside of
 12 Practice Fusion’s EMR software. The banner ads would appear when a prescriber was seeing a
 13 patient with certain health conditions, and the Purdue ads would appear with the patient’s EHR
 14 suggested pain-related content (for instance, a reference to the patient’s “pain symptoms.”). Three
 15 of the banner ads were for OxyContin, two were for Butrans.

17 745. After a few months, because of compliance concerns, Purdue paused the banner
 18 advertisement initiative, but in December 2013, Publicis made the case for continuing the initiative,
 19 and told Purdue, “Practice Fusion is the only partner that offers Banners within workflow prior to
 20 making a prescribing decision. Helps to increase awareness – and ultimately sales.”⁵⁶⁵

22 746. Meanwhile, Practice Fusion continued to solicit business from Purdue directly. In
 23 May 2014, for instance, Practice Fusion sent a news article to Purdue about Practice Fusion’s
 24 implementation of a CDS program for a vaccine manufacturer. The article was forwarded internally
 25 at Purdue to the new CEO, Mark Timney, who had been appointed CEO four months prior. Timney
 26 responded, “Thanks. The key is understanding how it grows or protects scripts.”⁵⁶⁶

28 ⁵⁶⁵ Massachusetts Publicis Complaint Para. 103.

⁵⁶⁶ Practice Fusion Information at Para. 28.

v. **CDS Alerts: Circumventing No-Sees, Influencing Prescribing, Making Money**

747. What is a CDS Alert? A doctor using Practice Fusion’s software would see a message “alerting the healthcare provider that, given the particular personal health information and circumstances of the patient before the provider at that moment, the provider should consider certain clinical information, perform certain tests or assessments, and complete certain documentation.”⁵⁶⁷

748. Do CDS alerts work?⁵⁶⁸ At a 2016 seminar for pharmaceutical companies put on by Ogilvy (another advertising agency, owned by Publicis competitor WPP), Practice Fusion presented, and gave the audience an example of the of power of the clinical decision support program.⁵⁶⁹

Practice Fusion, a cloud-based EHR provider, offered an example in which it launched an obesity clinical decision support program. The HER notified physicians with messages at the point of care about recording patients’ BMI stats and, if high, noting a treatment plan. The program reached more than 50,000 physicians and 3.7 million patients resulting in 25,000+ more patient plans, **which was a 5-fold increase.**

749. Why do CDS alerts work? Well, “the closed system of EHR’s... means the marketing and communications from pharma to physicians are not scattershot web ads, but much more targeted inside communications that can inform doctors at a critical moment.”⁵⁷⁰ “Presenter

⁵⁶⁷ Practice Fusion Information at Para. 17.

⁵⁶⁸ “Work,” in the sense of making money for the pharmaceutical company. ROI is the relevant metric. If the product cannot increase sales for the pharmaceutical company that pays Practice Fusion, no pharmaceutical company will pay Practice Fusion money, and the company would go broke or have to “pivot” to another business model and pray for rain. Practice Fusion was not a non-profit, nor a B Corp. It was in business to make money.

⁵⁶⁹ Beth Snyder Bulik, “Ogilvy CommonHealth takes deep dive on EHR as a marketing strategy for pharma clients,” *Fierce Pharma*, May 9, available at: <https://www.fiercepharma.com/marketing/ogilvycommonhealth-takes-deep-dive-ehr-as-a-marketing-strategy-for-pharma-clients> (emphasis added).

⁵⁷⁰ Beth Snyder Bulik, “Ogilvy CommonHealth takes deep dive on EHR as a marketing strategy for pharma clients,” *Fierce Pharma*, May 9, available at: <https://www.fiercepharma.com/marketing/ogilvycommonhealth-takes-deep-dive-ehr-as-a-marketing-strategy-for-pharma-clients> (emphasis added).

1 after presenter noted not only the value of EHRs but also that using them needs to be thought of as
 2 a strategy, not just a tactic or channel.”⁵⁷¹

3 750. Could CDS alerts be used as a strategy (or tactic) to maximize sales of a controlled
 4 substance that the planners know is causing widespread addiction, abuse, and death? Yes.

5 751. Were they? They were.

6 752. In late 2015, Purdue gave its approval to move forward with the Pain CDS alert
 7 program. Because the overall goal of the program was to increase the size of the *overall* ERO
 8 market, each of Purdue’s three ERO brands split the cost of the Practice Fusion program.

9 753. By 2016, Purdue and Practice Fusion were working to use CDS alerts for the
 10 “objective” to “Grow ERO prescriptions within the Practice Fusion eHR.” Publicis estimated that
 11 the return on investment (ROI) on the CDS alerts would be 2:1.⁵⁷² An additional \$2 million in
 12 annual revenue was possible by using Practice Fusion to convert IRO patients to ERO patients, but
 13 it would cost \$1 million annually in payments to Practice Fusion in order to obtain that additional
 14 revenue:
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23 ⁵⁷¹ Beth Snyder Bulik, “Ogilvy CommonHealth takes deep dive on EHR as a marketing strategy for pharma clients,”
 24 *Fierce Pharma*, May 9, available at: <https://www.fiercepharma.com/marketing/ogilvycommonhealth-takes-deep-dive-ehr-as-a-marketing-strategy-for-pharma-clients> (emphasis added).

25 ⁵⁷² Practice Fusion performed its own ROI analysis of the Pain CDS program for Purdue, and estimated that Purdue
 26 would enjoy a decidedly rosier 5.8 to 7.8 times its cost. Practice Fusion Information at Para. 37. Just like Publicis,
 27 Practice Fusion was at all times focused on delivering ROI for Purdue. In an April 22, 2015, internal email, a Practice
 28 Fusion employee conceded, “Since this is being sent to a marketing audience the idea of ROI has to be part of the plan
 to justify the costs of the program.” Practice Fusion Information at Para. 42.

Notably, this ROI analysis was left *out* of the written presentations that Practice Fusion provided to Purdue, as it would
 raise compliance concerns. “Don’t include the ROI in the [written] proposal. We’ll walk the client the ROI,” advised
 the same employee who stated that “the ROI has to be part of the plan.” Practice Fusion Information at Para. 43. Instead,
 Practice Fusion “voiced over” the “commercial impact” of its proposed program, instead of creating a paper trail.

Estimated ROI

Patients data captured within Practice Fusion eHR:

Number of Patients with Chronic Pain taking IRO	1,100,000
Number with average Pain Score of 5+	150,000
% Switched as a result of Quality Score Initiative	15%
Patients switched to ERO	22,500
Purdue Share of switches	25%
Average value of Switch in Purdue Revenue	\$350
Revenue Generation	\$2,000,000
Investment	\$1,000,000
ROI	2:1

Butrans
Buprenorphine Transdermal Patch

754. Practice Fusion and Purdue entered into a Statement of Work on March 1, 2016, to provide a CDS program “directed at chronic pain management treatment with immediate release opioids and chronically used NSAIDs.”⁵⁷³

755. The contract stated that the “Parties agree and acknowledge that the collaboration project will follow national evidence-based guidelines, and will not encourage the prescribing or utilization of Purdue-specific product or services.”⁵⁷⁴ Both Practice Fusion and Purdue knew at the time of contract formation this mutual representation was false. In fact, “national evidence-based guidelines” such as the CDC Guidelines released on March 15, 2016, were known to the Parties while the CDS was designed and implemented, but those guidelines were ignored. Likewise, a 2016 *New England Journal of Medicine* article entitled “Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies counseled against the use of opioids for chronic pain, where the benefits of opioids were “much more questionable” than in the acute treatment context. Purdue and Practice

⁵⁷³ Practice Fusion Information at Para. 75.

⁵⁷⁴ Practice Fusion Information at Para. 78.

1 Fusion reviewed the article but ignored its conclusions. Instead, they designed the CDS alerts to
2 *convert* users of IROs to EROs for long-term maintenance of chronic pain.

3 756. Purdue’s marketing team – not Purdue’s medical experts – worked with Practice
4 Fusion to *design* the CDS and determine its functionalities. For instance, the CDS was designed to
5 incorporate patient’s Pain Score and a brief pain inventory (“BPI”), and Purdue’s marketing staff
6 also contributed to the design of the Care Plan options presented within the CDS, and the logic of
7 the CDS software functionality itself.⁵⁷⁵ “BPI can increase ERO use,” Purdue noted.⁵⁷⁶

9 757. The CDS program was launched on the Practice Fusion platform in early July 2016.
10 The final pain CDS contained three separate alerts: (1) the first alert urged the healthcare provider
11 to record a pain score; (2) the second alert recommended that healthcare providers take a brief pain
12 inventory (“BPI”) of patients that met a certain threshold, for patients who had a chronic pain
13 diagnosis, and for patient who recorded two or more pain scores of four or more in the previous
14 three months (utilizing a zero to ten point scale); (3) the third alert suggested the creation of a follow
15 up plan to treat the patient’s pain, which alert appeared when a patient reported a pain scale of four
16 or higher within four months, or if a patient with chronic pain had a BPI contemplated.

18 758. The pain CDS alert implemented by Practice Fusion deviated from established
19 medical guidelines by directing providers to record a treatment plan only when pain was classified
20 as chronic or was above a certain threshold over a period of time. It did not incorporate the
21 substance of the New England Journal of Medicine article from which the CDS sourced a list of
22 treatment options.

24 759. Moreover, the Clinical Quality Measures (“CQM”) performance standards require
25 providers to record a treatment plan any time the pain assessment was documented as positive.
26 Contrary to accepted medical practice, the pain CDS alert listed EROs as a treatment option on
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28 ⁵⁷⁵ Practice Fusion Information at Para. 90.

⁵⁷⁶ Practice Fusion Information at Para. 91.

1 equal footing with IROs and non-opioid therapy. Likewise, it also listed EROs as a treatment option
 2 for opioid naïve patients without regard to whether the provider had the adequate expertise to
 3 prescribe EROs.

4 760. As the CDS alerts went live, Practice Fusion kept Purdue updated on progress.
 5 Practice Fusion told Purdue that through November 30, 2016, the pain CDS alert had produced
 6 alerts during 21 million patient visits, involving 7.5 million patients and 97,000 healthcare
 7 providers.

8 761. Practice Fusion further indicated that since its Pain CDS alerts went into effect
 9 “there is a general shift toward EROs from IROs,” the biggest impact recorded “within Emergency
 10 Medicine, Orthopedics, and Pain Medicine.”

11 762. The Pain CDS alert was live on the Practice Fusion platform from early July 2016
 12 to the spring of 2019. The Pain CDS alerted more than 230,000,000 times during this period.
 13 Physicians wrote hundreds of thousands of ERO prescriptions after one of the Pain CDS alerts had
 14 been triggered. Moreover, healthcare providers who received Practice Fusion’s Pain CDS alerts
 15 prescribed EROs at a higher rate than those that did not.⁵⁷⁷

16 **vi. Guilty**

17 763. In January 2020, Practice Fusion paid \$145 million and entered into a deferred
 18 prosecution agreement with the Department of Justice for these CDS alerts and its work with
 19 Purdue.⁵⁷⁸ Nine months later, Purdue pled guilty for conspiring with Practice Fusion to violate the
 20 Anti-Kickback Statute by paying Practice Fusion for the CDS alerts which were intended to

21 ⁵⁷⁷ See Practice Fusion Information, at Paragraph 115.

22 ⁵⁷⁸ Press Release, Department of Justice, “Electronic Health Records Vendor to Pay \$145 Million to Resolve Criminal
 23 and Civil Investigations, Practice Fusion Inc. Admits to Kickback Scheme Aimed at Increasing Opioid Prescriptions”,
 24 Department of Justice (Jan. 27, 2020), available at: <https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0> (describing Practice Fusion’s conduct as “abhorrent” and
 25 noting Practice Fusion and Purdue “illegally conspired to allow [Purdue] to have its thumb on the scale at precisely the
 26 moment a doctor was making an incredibly intimate, personal, and important decisions about a patient’s medical care,
 27 including the need for pain medication and prescription amounts.”)

1 increase sales of Purdue's drugs.⁵⁷⁹ Then, on March 8, 2021, Practice Fusion's former Director of
 2 National Accounts, Steven Mack, pled guilty to one count of attempting to obstruct a federal
 3 investigation into the relationship between Practice Fusion and Purdue.⁵⁸⁰

4 **vii. Another *Mea Culpa***

5 764. "I was horrified."

6
 7 765. So wrote Ryan Howard, co-founder and former Chairman and CEO of Practice
 8 Fusion, describing his reaction to "encountering some staggering news:" "Practice Fusion, a
 9 company I founded in 2005 and left in 2015, had reached a settlement with the DOJ for suddenly
 10 partnering with an opioid manufacturer, and for encouraging doctors on the platform to prescribe
 11 opioids to patients."⁵⁸¹

12 766. Howard "founded [Practice Fusion] in 2005 and was its Chairman and CEO until
 13 2015... Under Ryan's leadership the company raised \$134 million in capital Kleiner Perkins
 14 Caulfield & Byers... Deerfield Management Company [and others] to fuel its rapid growth."⁵⁸²

15 767. Howard noted that Practice Fusion "advertised to doctors *230 million times* to
 16 prescribe opioids," and concluded that his "successors" fell "prey to the allure of capital over human
 17 lives."⁵⁸³ He minced no words regarding the appropriate outcome for his "successors" at Practice
 18 Fusion for allowing the company to partner with Purdue: "Following my departure in 2015, my
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23 ⁵⁷⁹ Press Release, "Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid
 24 Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family," Department of Justice,
 October 21, 2020, *available at*: <https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid>

25 ⁵⁸⁰ Press Release, "Former Practice Fusion Sales Executive Pleads Guilty to Obstructing Government Investigations
 26 into Purdue Pharma and Practice Fusion," Department of Justice, March 8, 2021, *available at*:
<https://www.justice.gov/usao-vt/pr/former-practice-fusion-sales-executive-pleads-guilty-obstructing-government>

27 ⁵⁸¹ Ryan Howard, "How to Prevent Your Company from Being Used for Evil From a Founder Who's Been There,"
Entrepreneur, November 28, 2020, *available at*: <https://www.entrepreneur.com/article/359624>

28 ⁵⁸² See <https://www.practicefusion.com/practice-fusion-founders/>

⁵⁸³ Ryan Howard, "How to Prevent Your Company from Being Used for Evil From a Founder Who's Been There,"
Entrepreneur, November 28, 2020, *available at*: <https://www.entrepreneur.com/article/359624> (emphasis in original).

1 successors seemingly adopted a new mission – they allowed the [Purdue] partnership to take root
 2 – and for this, I suggest they experience the full retribution of our justice system.”⁵⁸⁴

3 768. Howard suggested that other entrepreneurs and founders of companies look into
 4 registering as benefit corporations, or B corporations, in order to prevent their creation from “being
 5 used for evil.” He also provided the following “full disclosure.”⁵⁸⁵
 6

7 I was never contacted by the DOJ, or any other authority, regarding Practice
 8 Fusion’s investigations. Likewise, I was not part of any conversation with any
 9 opioid manufacturer while I was CEO. The referenced partnership occurred in 2016,
 after my departure, as detailed in the official DOJ Report (p. 18).

10 769. Like the Sackler’s before him, Howard desired to distance himself from Purdue
 11 Pharma. But, as noted above, Practice Fusion’s relationship began in the fall of 2012, and Howard
 12 was CEO for approximately 2 years while the company partnered with and serviced Purdue. In the
 13 fall of 2012, Purdue was “working with Practice Fusion to conduct a pilot (test) with Butrans
 14 advertising on the EHR (electronic health record) site to determine if banner ads work at driving
 15 traffic to our e-marketing collateral (websites, savings cards online, patient education downloads,
 16 etc.). The strongest interest is in seeing if we can improve coupon and co-pay program
 17 utilization.”⁵⁸⁶
 18

19 770. And as early as September 13, 2012, Ryan Howard [REDACTED]
 20 [REDACTED]
 21 [REDACTED]
 22 [REDACTED]
 23 [REDACTED]
 24 [REDACTED]
 25
 26

⁵⁸⁴ Ryan Howard, “How to Prevent Your Company from Being Used for Evil From a Founder Who’s Been There,”
 27 *Entrepreneur*, November 28, 2020, available at: <https://www.entrepreneur.com/article/359624>

⁵⁸⁵ Ryan Howard, “How to Prevent Your Company from Being Used for Evil From a Founder Who’s Been There,”
 28 *Entrepreneur*, November 28, 2020, available at: <https://www.entrepreneur.com/article/359624>

⁵⁸⁶ PPLPC018000741102

1 [REDACTED]
 2 [REDACTED]
 3 771. Then, on February 25, 2014, [REDACTED]
 4 [REDACTED]
 5 [REDACTED]
 6 [REDACTED]
 7 [REDACTED]
 8 [REDACTED]⁵⁸⁸

9 772. In other words, [REDACTED]
 10 [REDACTED] Howard
 11 wrote, “I was not part of any conversation with any opioid manufacturer while I was CEO.”⁵⁸⁹
 12 [REDACTED]
 13 [REDACTED] Maybe he forgot.⁵⁹⁰ Howard’s words of wisdom
 14 to other founders regarding preventing their companies being “used for evil” are heartfelt,
 15 nonetheless.
 16

17 773. On August 18, 2015, Ryan Howard stepped down from his role as CEO of Practice
 18 Fusion and became Chairman of the Board. The Chief Commercial Officer, Tom Langan, replaced
 19 Howard as CEO. Langan had joined Practice Fusion only one year before.⁵⁹¹
 20

21 774. Within months of Howard’s departure, Practice Fusion hired JPMorgan Chase to
 22 explore the possibility of the company’s initial public offering at a valuation range of \$1.1 to \$1.5
 23

24 ⁵⁸⁷ PPLPC022000561019

25 ⁵⁸⁸ PPLPC021000631187

26 ⁵⁸⁹ Ryan Howard, “How to Prevent Your Company from Being Used for Evil From a Founder Who’s Been There,”
Entrepreneur, November 28, 2020, available at: <https://www.entrepreneur.com/article/359624>

27 ⁵⁹⁰ Likewise, Howard may have forgotten [REDACTED]
 28 [REDACTED] See MNK-

71_0006314898; MNK-T1_0006316021.

⁵⁹¹ Mark Sullivan, “Practice Fusion CEO Ryan Howard steps down, becomes chairman of the board,” *Venture Beat*,
 August 18, 2015, available at: <https://venturebeat.com/2015/08/18/practice-fusion-ceo-ryan-howard-steps-down-becomes-chairman-of-the-board/>

1 billion valuation in 2017. The valuation was based on projected annual revenues in 2018 of between
 2 \$155 million and \$181 million.⁵⁹² Its actual annual revenue in 2015, the year Practice Fusion
 3 engaged its financial advisors to explore sales options, was approximately \$50 million.⁵⁹³

4 775. Around the same time, however, Practice Fusion was seeking other options. Practice
 5 Fusion's board hired Evercore, an investment bank, in November 2015 to solicit interest from
 6 people who might want to buy Practice Fusion whole. Interested parties indicated a bid range for
 7 Practice Fusion between \$50 million to \$225 million, or around 0.5% of the IPO valuation.⁵⁹⁴

8 776. Four months after engaging Evercore and obtaining the low estimated offers,
 9 Practice Fusion was eager to show greater profitability as soon as possible so as to close the gap
 10 between the low valuations anticipated in a whole company sales transaction versus the billion
 11 dollar company it wanted to be in the event of an IPO.
 12

13 777. In February 2016, Practice Fusion fired one quarter of its workforce. Howard's
 14 successor, Langan indicated the downsizing was necessary "to get the company to a profit, at the
 15 same time that the low-priced acquisition offers were starting to accumulate."⁵⁹⁵
 16

17 778. It was within this context, with Practice Fusion desperately seeking near term
 18 revenue in order to validate an inflated valuation of the company, that Practice Fusion partnered
 19 with Purdue, who was likewise willing to pay top dollar in order to obtain its *own* "near term"
 20 growth. The two companies needed each other. For example, in discussing the proposed CDS alert
 21

22
 23 ⁵⁹² Katie Benner, "Practice Fusion Said to Hire JPMorgan Chase to Explore I.P.O.," *New York Times*, January 19, 2016,
 24 available at: <https://www.nytimes.com/2016/01/20/business/dealbook/practice-fusion-said-to-hire-jpmorgan-chase-to-explore-ipo.html>

25 ⁵⁹³ Christina Farr, "Employees at Practice Fusion expected IPO riches, but got nothing as execs pocketed millions,"
 26 *CNBC*, January 23, 2018, available at: <https://www.cnbc.com/2018/01/23/practice-fusion-workers-got-nothing-in-deal-as-execs-made-millions.html>

27 ⁵⁹⁴ Christina Farr, "Employees at Practice Fusion expected IPO riches, but got nothing as execs pocketed millions,"
 28 *CNBC*, January 23, 2018, available at: <https://www.cnbc.com/2018/01/23/practice-fusion-workers-got-nothing-in-deal-as-execs-made-millions.html>

⁵⁹⁵ Christina Farr, "Employees at Practice Fusion expected IPO riches, but got nothing as execs pocketed millions,"
CNBC, January 23, 2018, available at: <https://www.cnbc.com/2018/01/23/practice-fusion-workers-got-nothing-in-deal-as-execs-made-millions.html>

1 program with Purdue, Practice Fusion’s Senior Vice President on May 11, 2015, noted that there
2 was “urgency” for Practice Fusion to generate revenue.⁵⁹⁶

3 779. Ultimately, Practice Fusion was sold to Allscripts, another EHR vendor, on January
4 8, 2018, for \$100 million, more than 90% less than their projected IPO valuation, in “a
5 disappointing fire sale.”⁵⁹⁷

6
7 **o. ZS – The Salesforce Specialists**

8 780. Management consulting is the business of providing solutions to corporate clients.
9 “Business consulting is really focused on solving our clients’ business problems, and it is a very
10 diverse set of issues that we might tackle, for example, ‘where are the growth the growth
11 opportunities in our business, and how to we go after them,’ to something very specific, like ‘what
12 is the comp design that we should put together to incentivize our sales representatives next
13 quarter,’” explained Kelly Tousi, a Principal at ZS Associates.⁵⁹⁸ “That’s a wide range, as you can
14 imagine, and we do everything in between,” she said.⁵⁹⁹

15 781. Solutions take many forms, depending on and tailored to the client’s needs.
16 “Management consulting includes a broad range of activities, and the many firms and their
17 members often define these practices quite differently.”⁶⁰⁰

18 782. As described above, broadly speaking, there are two schools of management
19 consulting, namely “Strategy Consulting” and “Implementation Consulting.” ZS engages in both.
20
21
22
23

24 ⁵⁹⁶ Practice Fusion Information at Para. 45.

25 ⁵⁹⁷ Christina Farr, “Practice Fusion, once headed for \$1.5 billion valuation, ends in ‘disappointing’ fire sale,” *CNBC*,
January 8, 2018, available at: <https://www.cnbc.com/2018/01/08/practice-fusion-acquired-by-allscripts-for-100-million-in-cash.html>

26 ⁵⁹⁸ See “Business Consulting at ZS: learn how ZS recruits and interviews talent,” ZS Associates, March 16, 2018,
available at <https://www.youtube.com/watch?v=YZ3ZjARBnrI>

27 ⁵⁹⁹ *Id.*

28 ⁶⁰⁰ Arthur Turner, *Consulting is More Than Giving Advice*, Harvard Business Review, September 1982, available at:
<https://hbr.org/1982/09/consulting-is-more-than-giving-advice>.

1 783. ZS describes itself as “a professional services firm that works side by side with
2 companies to help develop and deliver products that drive customer value and company results.”⁶⁰¹
3 “Impact where it matters,” the ZS webpage declares.⁶⁰² ZS describes its impact as results, not just
4 ideas. “That’s why we partner with our clients from strategy to implementation and beyond.”⁶⁰³

5
6 784. Consistent with the origins of ZS in academia, the company’s initial focus was on
7 building models that could be used by their clients to drive decision-making regarding salesforce
8 structure and operations. As the founders explain, “early in our modeling careers in the 1970’s, our
9 thinking was centered on models, and we believed that the model was a large and prominent art of
10 solving sales-resource-optimization problems.”⁶⁰⁴

11 785. Like many consulting firms, ZS performs both strategy and implementation work
12 for its clients. But what sets ZS apart is that it has developed a particular niche in offering these
13 services in the context of pharmaceutical sales and marketing. ZS specializes in the optimization
14 of pharmaceutical sales forces in order to maximize sales and profit. In fact, ZS boasts that, “[i]n
15 its first three years, ZS helped eight of the 10 largest pharmaceutical companies in the world align
16 territories and resize their sales forces. By 2011, ZS worked with 40 of the 50 largest drug makers
17 in healthcare and 17 of the 20 largest medical device makers.”⁶⁰⁵

18
19 786. In addition to developing overall sales and marketing strategies for specific drugs
20 and drug portfolios, ZS regards implementation work as a core component of its overall product
21 offerings to its clients. Indeed, implementation – and in some instances wholesale outsourcing of
22 key business functions to ZS – are included as a component of practically every project that ZS
23 takes on for a client.
24

25
26 ⁶⁰¹ See <https://twitter.com/ZSAssociates>.

27 ⁶⁰² *Id.*

⁶⁰³ See <https://www.zs.com/about/our-impact>.

28 ⁶⁰⁴ See Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, Interfaces 31:3, Part 2 of 2, Pg. S35-36, May-June 2001.

⁶⁰⁵ See <https://www.zs.com/about/our-story>.

1 787. In the broadest of generalities, then, ZS’ business model, as a provider of strategy
2 and implementation consulting services to the pharmaceutical industry, is to partner with clients to
3 pursue business objectives identified by ZS. Once the objective is identified, the client and ZS then
4 engage in concerted action, as a seamless and cohesive unit, in order to implement the necessary
5 means to achieve the objectives for the client.

6
7 788. Beyond these traditional consulting services, ZS Associates are also known to serve
8 as thought leaders by authoring articles or providing soundbites or quotes in order to influence
9 perceptions in their client’s favor. For example, when physician’s offices began restricting access
10 to sales representatives, ZS joined with manufacturers to create content designed to counter this
11 movement.⁶⁰⁶

12
13 789. ZS optimizes pharmaceutical sales forces for the explicit purpose of increasing sales
14 and profit for the manufacturer client. In 2001, the founders of ZS published a paper entitled “Sales-
15 Force Decision Models: Insights from 25 Years of Implementation.” Describing ZS specialist
16 expertise, the founders stated, “Over 25 years, we have developed many sales-force and modeling
17 insights through over 2,000 projects with several hundred selling organizations in over 50 countries
18 ... Two to three percent of all of the field salespeople in the US have been touched by the results.
19 The firms had pressing issues that required quick attention. Companies sought help when merging
20 separate selling organizations, when launching new products, when facing deregulation, or when
21 faltering in performance.”⁶⁰⁷

22
23 790. In 2013, Chris Wright, ZS’ current Chief Executive Officer, explained to the *New*
24 *York Times*: “There’s a group of geeks, if you will, who are running the numbers and helping the
25

26
27 ⁶⁰⁶ See George Chressanthi et. al., *Can Access Limits on Sales Representatives to Physicians Affect Clinical*
28 *Prescription Decisions? A Study of Recent Events With Diabetes and Lipid Drugs*, *The Journal of Clinical*
Hypertension, Vol. 14, No. 7, July 2012, available at: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1751-7176.2012.00651.x>

⁶⁰⁷ *Id.* at S9.

1 sales guys be much more efficient.”⁶⁰⁸ The effect is “what would happen if Arthur Miller’s Willy
 2 Loman met up with the data whizzes of Michael Lewis’s ‘Moneyball.’”⁶⁰⁹

3 791. Wright was only a managing director at ZS when he provided his comments to the
 4 *Times* in 2013. In his 25 years at ZS, according to an “Impact Fact” described on ZS’ website,
 5 “Chris has helped dozens of pharmaceutical companies differentially resources their sales
 6 deployments, leading to multibillion-dollar industry cost savings.”⁶¹⁰

7 792. By exploiting “vast databases of patient and doctor information,” companies like ZS
 8 can provide advanced analytics capabilities to clients to maximize sales efforts. “They know
 9 whether patients are filling their prescriptions – and refilling them on time. They know details of
 10 patients’ medical conditions and lab tests, and sometime even their age, income and ethnic
 11 backgrounds.”⁶¹¹

12 793. ZS cannot drive customer value or company results, however, if its work is placed
 13 in a drawer and ignored. As such, ZS does not merely provide advice or models to clients. Instead,
 14 it works “side by side” with them to achieve results the client alone cannot. This reality was
 15 recognized early on in the history of ZS. “Over the years, we have realized that we spend much
 16 more energy on other activities, such as articulating the issues, building databases, and dealing with
 17 change management and implementation. For example, in the geographic deployment work we
 18 have done, we spend over 95 percent of the time in activities *unrelated to model building*.”⁶¹²

19 794. Likewise, clients of ZS do not wish to pay top dollar for specialized management
 20 consulting services regarding their crucial sales and marketing practices merely for suggestions
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 26 ⁶⁰⁸ Katie Thomas, “Pills Tracked from Doctor to Patient to Aid Drug Marketing,” *New York Times*, May 16, 2013,
 available at: <https://www.nytimes.com/2013/05/17/business/a-data-trove-now-guides-drug-company-pitches.html>

27 ⁶⁰⁹ *Id.*

⁶¹⁰ See <https://www.zs.com/about/our-people/Chris-Wright>

28 ⁶¹¹ Katie Thomas, “Pills Tracked from Doctor to Patient to Aid Drug Marketing,” *New York Times*, May 16, 2013,
 available at: <https://www.nytimes.com/2013/05/17/business/a-data-trove-now-guides-drug-company-pitches.html>

⁶¹² *Id.* at S36.

1 about how best to do things on their own. Just as an automobile manufacturer does not hire an
 2 airbag company to advise it on how to design, create, and install safe airbags in its cars, but instead
 3 just hires the airbag company to sell it safe airbags; pharmaceutical manufacturers hire consultants
 4 like ZS to implement mission-critical salesforce tasks they do not have the capability to perform
 5 on their own.

7 795. ZS speaks in terms of “optimizing” its clients’ efforts to sell its products. ZS’ clients
 8 are for-profit companies, and “optimization” implies a specific variable you are optimizing. In the
 9 case of ZS, the variable is the amount of money the client can make.⁶¹³

10 796. ZS applied its hard-won expertise to multiple clients, “optimizing” their salesforces
 11 for the purposes of maximizing the profits derived from selling controlled substances.

12 **i. The Salesforce – Pharma’s Engine**

13 797. Sales forces are a major component of pharmaceutical companies’ operations.
 14 Indeed, they are the core of the industry. In 2007, it was estimated that there were 100,000
 15 pharmaceutical sales representatives in the United States pursuing approximately 200,000
 16 prescribers.⁶¹⁴

17 798. These armies of sales reps are employed by pharmaceutical companies and detailed
 18 to health care providers to market the companies’ drugs to those with the power to prescribe them.
 19 By 2000, at the outset of the opioid crisis, pharmaceutical companies were spending in excess of
 20 \$15 billion annually promoting drugs, with 84% of the total spend directed at detailing sales
 21 representatives to prescribers, drug samples, and ads in medical journals.⁶¹⁵

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 27 ⁶¹³ See <https://www.zs.com/solutions/artificial-intelligence-and-analytics/analytics> (Touting ZS’s “Analytics
 optimization” solutions, ZS emphasized, “You need to ensure that you’re investing in the right analytics capabilities,
 tapping into the right data sets and maximizing your ROI with key insights that drive business transformations.”)

28 ⁶¹⁴ Tobias L. Milrood, *When Drug Representatives Go Too Far*, American Association for Justice, February 2007.

⁶¹⁵ M.B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers*, 346 New England J. Med. 498 (2002).

799. “Because of the large size of pharmaceutical sales forces, the organization, management, and measurement of effectiveness of the sales force are significant business challenges.”⁶¹⁶ This is ZS’ niche. ZS tells its clients how to optimize, incentivize, and deploy these armies of pharmaceutical sales representatives for the purpose of maximizing revenue. In the words of ZS’ founders, “[t]hat marketing investment drives sales is a fundamental principle supported by data.”⁶¹⁷ ZS has observed the statistically significant relationship between sales force effort and sales of pharmaceuticals, as depicted in the following scatter plot⁶¹⁸:

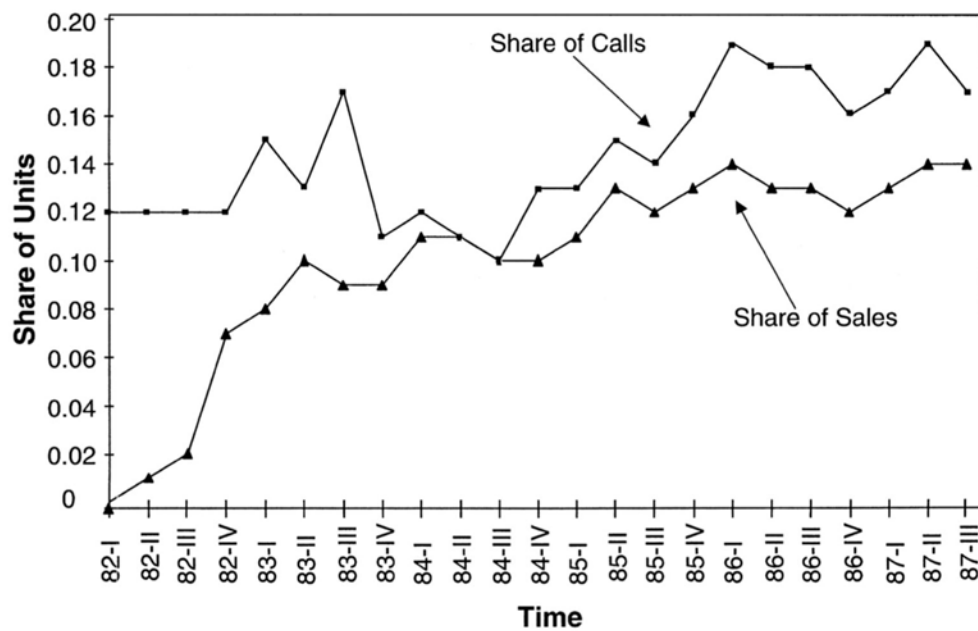


Figure 2: This scatter plot using longitudinal data shows a statistically significant relationship between sales-force effort and sales for a product sold by a pharmaceutical sales force. Every dot represents a quarter of the year.

800. ZS provided these services to numerous opioid manufacturers, which produced controlled substances known to be addictive at the time ZS advised them, for the explicit purpose of maximizing the sales and revenue of these deadly and addictive drugs during the pendency of a nationwide opioid crisis wrought by the over-selling of opioids by ZS’ clients.

⁶¹⁶ Tobias L. Milrood, *When Drug Sales Representatives Go Too Far*, American Association for Justice, February 2007.

⁶¹⁷ Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*, *Interfaces* 31:3, Part 2 of 2, Pg. S10, May-June 2001.*Id.* at S10.

⁶¹⁸ *Id.* at S12.

1 **ii. ZS – Pharma’s long-term partner**

2 801. Like many participants in the pharmaceutical consulting space, ZS does not merely
 3 provide advice to its clients on a one-off basis. Rather, according to ZS, a client relationship is
 4 “about results, not just ideas. That’s why we partner with our clients from strategy to
 5 implementation and beyond.”⁶¹⁹ “We work side-by-side with you at every stage to help you achieve
 6 success.”⁶²⁰ These partnerships are *long term*. For instance, ZS’ founders have observed that,
 7 “having worked with some managers *repeatedly for over a decade or more*, we have observed
 8 patterns in the ways managers use consulting assistance and models.”⁶²¹

9
 10 802. At ZS, “business consulting is really focused on solving our clients’ business
 11 problems, and it is a very diverse set of issues that we might tackle, for example you could be
 12 anything from ‘where are the growth opportunities in our business and how should we go after
 13 them,’ to something very specific, like ‘what is the comp design that we should put together to
 14 incentivize our sales representatives next quarter’? So that’s a wide range, as you can imagine; we
 15 do everything in between.”⁶²²

16
 17 803. In other words, ZS does not merely provide ideas and advice to its clients. Rather,
 18 it designs and implements sales force models aimed at the most efficient allocation of marketing
 19 spending and maximization of profits for their manufacturer clients. In fact, ZS’ recommendations
 20 are routinely implemented on such a systematic and industry-wide basis that ZS itself is now able
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 25 ⁶¹⁹ See <https://www.zs.com/about/our-impact>

26 ⁶²⁰ *Id.*

27 ⁶²¹ Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*,
 Interfaces 31:3, Part 2 of 2, Pg. S37, May-June 2001 (emphasis added).

28 ⁶²² See ZS Associates, “Business consulting at ZS: learn how ZS recruits and interviews talent,” *available at*:
<https://www.youtube.com/watch?v=YZ3ZjARBnrL>. Incidentally, the factors ZS articulates in its sales pitch as firm
 competencies – identifying growth opportunities and incentivizing the sales representatives – are *both* identified as
 principal origin points of the opioid epidemic by Dr. Van Zee as early as 2002.

1 to draw on its own history of implementing change for its clients, as a data set of its own worthy of
2 academic study.⁶²³

3 **iii. ZS services its clients**

4 804. Even though the marketing of OxyContin has been described as the “taproot” of the
5 opioid epidemic, Purdue was not the only manufacturer to zealously market their own opioids. Nor
6 was Purdue ZS’ only opioid client.
7

8 805. ZS provided similar services, as explained below, to fellow opioid manufacturers
9 Mallinckrodt Pharmaceuticals, Endo Pharmaceuticals, Teva Pharmaceuticals, and Johnson &
10 Johnson’s Janssen Pharmaceuticals. Consistent with its work for Purdue, ZS designed,
11 implemented, and optimized salesforce strategies to maximize the profits derived from selling a
12 controlled substance for practically every major opioid manufacturer. ZS’ client work is described
13 in individual detail below.
14

15 **1. Purdue**

16 806. As described above⁶²⁴, after 2007 Purdue was pursuing the Sackler’s goal of
17 maximizing near-term OxyContin sales so as to extract as much money from Purdue as possible in
18 order to diversify away from the dangerous “concentration of risk” that continued financial reliance
19 on Purdue represented for the billionaire family.
20

21 807. ZS happily agreed to help, and by [REDACTED] ZS and Purdue were working
22 together to increase sales of Purdue’s opioids. [REDACTED]

23 [REDACTED] based on ZS’ own independent research and unique methodologies,
24 including modelling expertise. Purdue adopted ZS’ strategies and worked closely with ZS to
25
26

27 ⁶²³ Prabhakant Sinha and Andris Zoltners, *Sales Force Decision Models: Insights from 25 Years of Implementation*,
28 Interfaces 31:3, Part 2 of 2, Pg. S18-19, May-June 2001 (“The repeated application of several normative sales-force-
decision models has produced a series of insights that have led to a number of valuable sales-force insights.”)

⁶²⁴ See Paragraphs 87-93, *supra*.

1 implement ZS' plan. Despite the strictures imposed upon Purdue by the Corporate Integrity
2 Agreement, OxyContin sales began to multiply.

3 808. ZS' relationship with Purdue lasted at least through [REDACTED] during which ZS engaged
4 in numerous projects for Purdue, each with the intent of maximizing sales and profits of Purdue's
5 controlled substances.

6 809. Purdue hired ZS for [REDACTED]
7 [REDACTED] These [REDACTED] were necessary in light of the Sackler family's – Purdue's
8 sole owners – decision to exit the opioid business in light of the perceived risks of staying there.

9 810. From the outset, [REDACTED]
10 [REDACTED] – an acknowledgement by both Purdue and ZS of the real-
11 world stakes at issue in ZS' work.

12 811. ZS' first known work for Purdue commenced in the final months of [REDACTED] and
13 focused on [REDACTED]

14 [REDACTED] One of the [REDACTED] ZS observed, was [REDACTED]
15 [REDACTED]
16 [REDACTED] In other
17 words, ZS would find ways to get prescribers to *change their prescribing behavior* by prescribing
18 more extended-release opioids for longer periods of time.

19 812. Once ZS identified the drivers behind these prescriber behaviors, ZS developed a
20 plan to "correct" the behavior in ways beneficial to Purdue, and, once adopted by the client, began
21 implementing changes at Purdue to increase OxyContin sales. ZS would "evaluate and determine
22 optimal sales and marketing strategy to support OxyContin," and would "draw an implementation
23 roadmap" incorporating "tangible action steps regarding identified OxyContin hurdles in terms of
24 sales, marketing, and managed care approach. ZS would also conduct "Solution Design
25
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1 Workshops” with Purdue’s staff regarding the best ways to undertake the changes in strategy
2 identified by ZS.

3 813. In [REDACTED]
4 [REDACTED] while Purdue was still bound by the Corporate Integrity
5 Agreement. This time ZS’ work related to [REDACTED]
6 [REDACTED]

7
8 814. The work took a holistic approach to Purdue’s entire sales and marketing efforts for
9 its pain portfolio, including OxyContin, MS Contin, and RyzoltTM.

10 815. In addition to working on Purdue’s existing pain portfolio, in [REDACTED] ZS assisted
11 Purdue in [REDACTED]
12 [REDACTED] At that early point in the opioid crisis, Purdue was already
13 interested in expanding into products for the treatment for opioid use disorder, which, according to
14 ZS, [REDACTED]
15

16 816. ZS focused on answering mission-critical questions for Purdue, including but not
17 limited to:

18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]

24 817. As always, ZS’ work included an implementation component, including
25 [REDACTED] and [REDACTED]
26 [REDACTED] ZS assured Purdue that
27 [REDACTED]
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818. In 2012,

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ZS agreed to

and

ZS agreed to address “key questions” like

Additionally, ZS undertook an analysis to

820. ZS conducted this work in conjunction with a core team of Purdue employees

821. By 2013, one year after Purdue was no longer shackled by the constraints of the 2007 Corporate Integrity Agreement that expired in 2013, Purdue also engaged with a separate consulting company, McKinsey & Company, Inc., to design a new company-wide sales and marketing approach. McKinsey’s proposals, initially dubbed *Project Turbocharge*, were eventually

1 rechristened *Evolve to Excellence* and were implemented by McKinsey and Purdue for the explicit
2 purpose of maximizing opioid sales despite the by-then obvious risks associated with selling as
3 much OxyContin as possible.

4 822. ZS worked in cooperation with McKinsey and Purdue to implement and continually
5 refine *Project Turbocharge*, including [REDACTED] McKinsey's
6 efforts to target the highest prescribers of OxyContin and blitz them with the newly turbocharged
7 sales force. ZS worked with an Executive Oversight Team and Project Management Office,
8 comprised of Purdue and McKinsey staff, to implement McKinsey's plans for Purdue.

9 823. That same year, despite significant headwinds, OxyContin sales finally peaked. The
10 restrictions on Purdue's sales and marketing methods contained in the Corporate Integrity
11 Agreement should have resulted in fewer overall OxyContin sales. Within five years of Purdue's
12 guilty plea, however, OxyContin sales tripled.

13 824. ZS played a crucial role in accomplishing this feat. It presented specific plans to
14 Purdue, which Purdue adopted and spent hundreds of millions of dollars implementing alongside
15 ZS and other consultants. The result: a final spasm of OxyContin sales before the inevitable decline
16 of the drug.⁶²⁵

17 825. In August of 2013, McKinsey urged, as part of the overall sales maximization
18 approach, that sales representatives should devote two-thirds of their time to selling OxyContin and
19 one-third of their time selling Butrans, another Purdue product. Previously, the split had been fifty-
20 fifty.

21 826. Two months later, [REDACTED] ZS sought to
22 answer the question, [REDACTED]
23 [REDACTED]
24 [REDACTED]

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28 ⁶²⁵ On February 10, 2018, Purdue announced that it is no longer marketing opioids, and disbanded its OxyContin sales force.

1 [REDACTED] Within months of McKinsey's recommendation that Purdue
2 should shift its resource allocation from a 50/50 split between OxyContin and Butrans to 2/3's
3 OxyContin and 1/3 Butrans, [REDACTED]
4 [REDACTED]
5 [REDACTED]

6 827. In other words, [REDACTED]
7 [REDACTED]

8 As stated earlier (and
9 exemplified here), the pharmaceutical industry is complex, and manufacturers do not do everything
10 themselves. Purdue continually sought the ongoing assistance of ZS and many others to achieve its
11 aims.

12 828. In conjunction with the ongoing implementation of McKinsey's *Evolve to*
13 *Excellence* at Purdue, ZS' relationship with Purdue flourished. With the rollout of *Evolve to*
14 *Excellence* in 2014, ZS was intimately involved in Purdue's sales transformation. [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]

19 The requests for
20 support were granular in their detail, including a [REDACTED]
21 [REDACTED] and [REDACTED]
22 [REDACTED]

23 which was work
24 necessary to implement the overall physician targeting strategy espoused and directed by McKinsey
25 at Purdue, such as the design of a [REDACTED]
26 [REDACTED]

27 829. ZS was not merely working on a project that McKinsey created and oversaw. ZS
28 routinely interacted with McKinsey consultants in furtherance of their mutual goal of maximizing

1 sales of Purdue's opioids. For example, on July 31, 2013, [REDACTED]

2 [REDACTED]
3 [REDACTED] A few weeks later, [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]

7 [REDACTED] Then, on October 15, 2013, [REDACTED]
8 [REDACTED]
9 [REDACTED]⁶²⁸ At the same
10 meeting, [REDACTED]
11 Two weeks later, [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 830. The following month, the Project Management Office recommended to the
16 Executive Oversight Team through which McKinsey and Purdue implemented E2E [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]

21 the email stated.⁶³³

22 831. Throughout this time period, [REDACTED]
23 [REDACTED]
24 [REDACTED]

25 ⁶²⁶ MCK-MDL1996-0219810

26 ⁶²⁷ MCK-MDL2996-0220115

27 ⁶²⁸ MCK-MDL2996-0077806

28 ⁶²⁹ MCK-MDL2996-0077806

⁶³⁰ MCK-MDL2996-0077733

⁶³¹ *Id.*

⁶³² MCK-MDL2996-0421514

⁶³³ *Id.* (emphasis added).

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
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5 832. By this time, ZS had also begun providing its AccessMonitor software for Purdue
6 to use. AccessMonitor is one example of a common tactic used by consultants to maintain an
7 ongoing revenue stream from its clients, separate and apart from traditional project-based work:
8 the development and marketing of “leave-behind” products, such as software applications, that are
9 sold to clients as tools that can be used by the business on an on-going and recurring basis, separate
10 and apart from the project-based consulting work that is ZS’ core offering.

11 833. As described by famed Harvard Business School Professor Clayton Christensen,
12 these sorts of “software and technology-based analytics and tools that can be embedded at a client,”
13 are a tool used by a consultancy to deepen its partnerships with clients and earn additional and
14 recurring revenue from them. Tools such as ZS’ AccessMonitor, Prof. Christensen noted, provide
15 “ongoing engagement outside the traditional project-based model” traditionally used by
16 consultants.⁶³⁵

17
18 834. By 2017, McKinsey was working on Project Scottsdale for Purdue. The goal of the
19 project was to “transform Purdue’s entire business model” by splitting Purdue’s assets into three
20 separate companies and downsizing the employee headcount at the companies by 500 people.⁶³⁶
21 Just like Project Turbocharge, ZS collaborated with McKinsey on Project Scottsdale. In a
22 December 2017 internal McKinsey email, McKinsey consultant Albert Lee reported to John Goldie
23

24
25 _____
26 ⁶³⁴ MCK-MDL2996-0326142 (emphasis added).

27 ⁶³⁵ Clayton Christensen, Dina Wang, and Derek van Bever, “Consulting on the Cusp of Disruption,” *Harvard Business Review*, October 2013, available at <https://hbr.org/2013/10/consulting-on-the-cusp-of-disruption>

28 ⁶³⁶ The Firm and the FDA: McKinsey & Company’s Conflicts of Interest at the Heart of the Opioid Epidemic, Interim Majority Staff Report, Committee on Oversight and Reform, U.S. House of Representatives, April 13, 2022, at Pg. 27, available at: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2022-04-13.McKinsey%20Opioid%20Conflicts%20Majority%20Staff%20Report%20FINAL.pdf>

1 and Amir Golan that work on re-sizing Purdue's sales forces pursuant to the goals of Project
 2 Scottsdale was "a WIP [work in progress] with ZS."⁶³⁷

3 835. In December of 2015, ZS' client Purdue agreed to a settlement with the State of
 4 Kentucky relating to the improper marketing of OxyContin and other Purdue products. Purdue
 5 agreed to pay \$24 million in conjunction with the settlement.
 6

7 836. Despite this second enforcement action against its client, ZS' work on Purdue's sales
 8 and marketing efforts continued unabated. Throughout its relationship with Purdue, ZS worked on
 9 core functions of Purdue's efforts to sell its drugs.

10 837. These core functions were previously identified as particular areas of concern with
 11 respect to Purdue's business conduct, and were specifically monitored and regulated under the 2007
 12 Corporate Integrity Agreement, which governed, *inter alia*:
 13

- 14 • "selling, marketing, promoting, advertising, and disseminating Materials
 15 or information about Purdue's products in compliance with all applicable
 16 FDA requirements, including requirements relating to the dissemination
 17 of information that is fair and accurate ... including, but not limited to
 information concerning the withdrawal, drug tolerance, drug addiction
 or drug abuse of Purdue's products;
- 18 • compensation (including salaries and bonuses) for Relevant Covered
 19 Persons engaged in promoting and selling Purdue's products that are
 20 designed to ensure that financial incentives do not inappropriately
 motivate such individuals to engage in the improper promotion or sales
 of Purdue's products; ...
- 21 • the process by which and standards according to which Purdue sales
 22 representatives provide Materials or respond to requests from HCP's
 23 [health care providers] for information about Purdue's products,
 24 including information concerning withdrawal, drug tolerance, drug
 25 addiction, or drug abuse of Purdue's products," including "the form and
 26 content of Materials disseminated by sales representatives," and "the
 27 internal review process for the Materials and information disseminated
 28 by sales representatives."⁶³⁸

⁶³⁷ MCK-MDL2996-0334687

⁶³⁸ See <https://s3.documentcloud.org/documents/6452110/2007-Purdue-Corporate-Integrity-Agreement.pdf> at pgs. 7-9.

1 838. In fact, under the terms of Paragraph II.C.1(b) of the Corporate Integrity Agreement,
 2 ZS, as a contractor to Purdue performing sales and marketing functions for the company, was a
 3 “Covered Person” subject to the strictures of the CIA.⁶³⁹

4 839. In addition to ZS’ “expertise and thought leadership,” ZS’ assumption of these
 5 obligations for Purdue involved the deployment of Javelin, its proprietary salesforce optimization
 6 software tool. Like AccessMonitor, described *supra*, Javelin was a software tool that ZS could
 7 embed with clients. With Javelin, a ZS client can “streamline sales performance management with
 8 a comprehensive platform that simplifies sales strategy management and helps you build and
 9 motivate a successful sales force.”⁶⁴⁰ The Javelin products include “suites” of software for the
 10 management and operation of Incentive Compensation (IC) and Call Planning (CP) functions.⁶⁴¹

11 840. Upon information and belief, all of Purdue’s then 712 sales representatives were
 12 licensed users of ZS’ trademarked Javelin suite of software solutions.

13 841. On October 20, 2020, Purdue entered into a plea agreement with the United States
 14 Department of Justice to plead guilty to improper marketing of OxyContin and other opioids,
 15 again.⁶⁴² This time the plea agreement concerned conduct from 2010 to 2018. ZS collaborated with
 16 Purdue on its sales and marketing practices [REDACTED] the time period relevant to Purdue’s second
 17 guilty plea.⁶⁴³

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 23 ⁶³⁹ The relevant language in the CIA provides: “Covered Persons” includes ... all contractors, subcontractors, agents,
 and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions ...
 on behalf of Purdue.” *Id.* at 2.

24 ⁶⁴⁰ See <https://www.zs.com/products/javelin>.

25 ⁶⁴¹ *Id.*

26 ⁶⁴² See <https://www.justice.gov/opa/press-release/file/1329576/download>

27 ⁶⁴³ On February 10, 2018, [REDACTED] Purdue
 28 announced that it is no longer marketing opioids, and disbanded its OxyContin sales force. “OxyContin maker stops
 promoting opioids, cuts sales staff,” *Reuters*, February 10, 2018, available at: <https://www.reuters.com/article/us-usa-opioids-purduepharma/oxycontin-maker-stops-promoting-opioids-cuts-sales-staff-idUSKBN1FU0YL> (“OxyContin
 maker Purdue Pharma LP said on Saturday that it has cut its sales force in half and will stop promoting opioids to
 physicians, following widespread criticism of the ways that drugmakers market addictive painkillers.”). As such, [REDACTED]

1 842. Purdue agreed to plead guilty to a dual-object conspiracy to defraud the United
2 States and violating the Food, Drug, and Cosmetic Act, 21 U.S.C. § 331, 353, among other charges,
3 relating to its opioid sales and marketing practices after the 2007 guilty plea.⁶⁴⁴ Purdue's co-
4 conspirators were not identified in the plea agreement.

5
6 843. Purdue's second guilty plea concerns Covered Conduct (as defined in the plea
7 agreement) relating to Purdue's sales and marketing efforts that directly implicates ZS in the
8 conspiracy. ZS' work for Purdue described in this Complaint was a core component of the sales
9 and marketing tactics that lead to Purdue's second guilty plea.

10 2. Mallinckrodt

11 844. Upon information and belief, around the same time ZS was working with Purdue to
12 implement McKinsey's *Project Turbocharge* to maximize OxyContin sales by continual
13 refinement of physician targeting and other sales and marketing tactics, ZS was also working with
14 another long-term client, Mallinckrodt, [REDACTED]
15 [REDACTED]
16 [REDACTED]

17 845. Mallinckrodt is the largest supplier of opioid pain medications and among the top
18 ten generic pharmaceutical manufacturers in the United States. In 2015, for instance,
19 Mallinckrodt's opioids accounted for approximately one quarter (25%) of the entire annual
20 production quota for controlled substances under DEA regulations. Mallinckrodt produced the
21 following branded and generic opioids:
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⁶⁴⁴ See <https://www.justice.gov/opa/press-release/file/1329576/download>

Product Name	Chemical Name
Exalgo	Hydromorphone hydrochloride, extended release
Xartemis XR ¹⁰⁴	Oxycodone hydrochloride and acetaminophen (extended release)
Roxicodone ¹⁰⁵	Oxycodone hydrochloride
Generic	Oxymorphone hydrochloride (extended release) (generic Opana)
Generic	Oxycodone (extended release) (generic OxyContin)
Generic	Morphine sulfate, extended release
Generic	Morphine sulfate oral solution
Generic	Oxycodone and acetaminophen (Percocet)
Generic	Hydrocodone bitartrate and acetaminophen (Vicodin)
Generic	Hydromorphone hydrochloride
Generic	Hydromorphone hydrochloride, extended release (Generic Exalgo)
Generic	Fentanyl transdermal system
Generic	Oral transmucosal fentanyl citrate
Methadose	Methadone hydrochloride
Generic	Methadone hydrochloride
Generic	Buprenorphine and naloxone

846. Previously, [REDACTED]

Mallinckrodt sought to use ZS' expertise to [REDACTED]

and to [REDACTED]

847. Mallinckrodt promoted Exalgo as having characteristics that made the drug less likely to be addictive or abused, despite the lack of FDA approval for the drug as "abuse-deterrent."

848. Then, on March 12, 2014, Mallinckrodt obtained FDA approval for Xartemis XR, its extended-release opioid tablet.⁶⁴⁵ Upon information and belief, by the time Mallinckrodt obtained approval to market its opioid, ZS had already established a long-term working relationship with Mallinckrodt regarding the sales and marketing of Mallinckrodt's portfolio of pain medications.

849. ZS was intimately involved [REDACTED] from the outset.

⁶⁴⁵ See "Xartemis receives approval: May reduce opioid abuse," Formulary Watch, March 28, 2014, [available at https://www.formularywatch.com/view/xartemis-xr-receives-fda-approval-may-reduce-opioid-abuse](https://www.formularywatch.com/view/xartemis-xr-receives-fda-approval-may-reduce-opioid-abuse)

1 850. In anticipation of Xartemis' launch, Mallinckrodt augmented its salesforce by
 2 adding hundreds of contracted sales representatives to promote the drug. CEO Mark Trudeau
 3 anticipated Xartemis would generate "hundreds of millions" in revenue for Mallinckrodt.⁶⁴⁶

4 851. In September, only months after FDA approval, ZS unveiled an overall sales and
 5 marketing strategy for the drug. The scope of the plan was all-encompassing, including overall
 6 global strategy as well as granular details of execution and implementation. Tactics to be deployed
 7 in ZS' plan included the deployment of marketing materials in the offices of health care providers
 8 (including "in-office patient education materials" meant for the consuming public), physician
 9 targeting and decile segmentation, a video series interviewing clinicians about the benefits of the
 10 drug, patient testimonials, a speaker program, patient co-pay cards, targeting promotion outreach
 11 to regional associations of physician assistants⁶⁴⁷, and other efforts to maximize sales and revenue.
 12 Many of these same tactics were weapons in Purdue's arsenal, designed by ZS.
 13

14 852. Part of ZS' plan [REDACTED]
 15 [REDACTED]
 16 [REDACTED]
 17 [REDACTED] in addition to [REDACTED]
 18 [REDACTED]
 19

20 853. ZS' [REDACTED]
 21 [REDACTED]
 22 [REDACTED]
 23

24 ⁶⁴⁶ See <https://www.bizjournals.com/stlouis/blog/health-care/2014/01/mallinckrodt-new-drug-should.html>

25 ⁶⁴⁷ This focus on physician's assistants is consistent with ZS' finding in an August 2016 report it issued, arguing that
 26 "[a]nother way to increase reps' chances for success is to expand the potential audience beyond the physician." ZS
 explained, "Other people on staff at the physician's office could be worthwhile targets for pharmaceutical messaging,
 such as nurse practitioners and physician assistants. *On average, people in these roles are incrementally more*
accessible than physicians." *Physicians Becoming More Restrictive About Rep Sales Calls; Digital Communications*
Picks Up, 28 No. 8 FDA Advertising & Promotion Manual News. 8, October 2016 (emphasis added).

27 ⁶⁴⁸ "TRx" is an abbreviation for the measurement of increase in "total prescriptions," meaning all new prescriptions
 28 **plus** refills on those prescriptions. "Growing TRx," in other words, means encouraging refills of new prescriptions.
 This approach to maximizing revenue by encouraging refills of controlled substances known to be addictive carried
 obvious risks.

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[REDACTED]

[REDACTED]

[REDACTED]

854. Ominously, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

855. Mallinckrodt encouraged its sales reps to aggressively market its new opioid by implementing ZS’ marketing and sales strategy. One supervisor urged the Xartemis sales force to “ATTACK” health care providers and informed representatives that they could obtain “big bonus

dollars” by waiting in front of doors of health care providers and using free trial offers to gain prescriptions.⁶⁴⁹

856. Another sales supervisor encouraged sales representatives that Xartemis “is the BEST opportunity to make lots of money! ! !”⁶⁵⁰

857. ZS designed and implemented the incentive compensation plan for Xartemis.

858. The above is even more alarming in light of the fact that ZS had been using its hub-like position among many manufacturers to develop a business intelligence tool by analyzing call note reports from over 45,000 sales reps across the country.⁶⁵¹ Given their ability to analyze the large amounts of data ZS possessed, ZS were the only ones with the keys to unlock the prescribing practices of each target physician.

859. Mallinckrodt repeatedly promoted Xartemis ZR as having physical properties that made the drug less likely to be addictive or abused, even though the drugs had never been approved by the FDA as abuse-deterrent. For instance, promotional materials provided to prescribers stated “Xartemis XR has technology that requires abuses to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients.”⁶⁵²

860. Not only had the FDA not approved Xartemis as an abuse-deterrent formulation, the marketing claims were false and misleading in that none of the characteristics of Xartemis address the most common form of opioid abuse: simple oral ingestion, swallowing the pill.

⁶⁴⁹ William K. Rashbaum, Roni Caryn Rabin and Danny Hakim, “Opioid Sales Reps Swarmed New York at Height of Crisis,” *New York Times*, April 19, 2019, available at <https://www.nytimes.com/2019/04/11/health/opioids-sacklers-new-york-purdue.html>

⁶⁵⁰ *Id.*

⁶⁵¹ See “Crossing the threshold: More than half of physicians restrict access to sales reps,” *ZS Associates*, September 1, 2015, available at: <https://www.zs.com/about/newsroom/crossing-the-threshold-more-than-half-of-physicians-restrict-access-to-sales-reps>

⁶⁵² See “Xartemis receives approval: May reduce opioid abuse,” *Formulary Watch*, March 28, 2014, available at <https://www.formularywatch.com/view/xartemis-xr-receives-fda-approval-may-reduce-opioid-abuse>

1 861. As stated above, the data and analytics capabilities of ZS, when tasked to the purpose
 2 of maximizing drug sales and revenue, should result in the unearthing of suspicious orders worthy
 3 of reporting to the DEA.⁶⁵³ Despite ZS working with Endo to assiduously study in granular detail
 4 the topic of where its pills are sold (and how to sell more of them), Endo nonetheless failed in its
 5 reporting obligations under the Controlled Substances Act.

7 862. In a July 2017 Memorandum of Agreement with the DEA and the Department of
 8 Justice, Mallinckrodt agreed that “at certain times during the Covered Time Period prior to January
 9 1, 2012, certain aspects of Mallinckrodt’s system to monitor and detect suspicious orders did not
 10 meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion
 11 Control to registrants [Mallinckrodt] dated September 27, 2006, and December 27, 2007.”⁶⁵⁴

13 3. Endo

14 863. ZS’ relationship with Endo Pharmaceuticals [REDACTED]
 15 [REDACTED]

16 864. Upon information and belief, [REDACTED]
 17 [REDACTED] months after Endo’s launch of Opana ER, its extended-release oxymorphone tablet in 2006.
 18 At the time, Endo’s marketing efforts were primarily focused on Opana ER, its branded extended-
 19 release oxymorphone hydrochloride tablet. Oxymorphone hydrochloride is three times as strong as
 20 morphine.

22 865. ZS’ first known work for Endo involved developing and implementing [REDACTED]
 23 [REDACTED]
 24 [REDACTED] ZS
 25 acknowledged.

27 ⁶⁵³ See *supra*, ¶ 64-65.

28 ⁶⁵⁴ See the July 2012 Memorandum of Agreement between Mallinckrodt and the DEA at <https://www.justice.gov/usao-edmi/press-release/file/986026/download>

1 866. ZS designed [REDACTED]

2 [REDACTED] Opana. This was crucial, as Endo required a [REDACTED]

3 [REDACTED] in order for Endo to [REDACTED]

4 867. Moreover, ZS was engaged not only [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 868. By 2009, [REDACTED]

10 [REDACTED] As such, ZS was tasked with

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 869. ZS' focus on ROI for its clients, described in Section D, above, is front and center

17 in the title of its July 16, 2012, presentation to Endo Pharmaceuticals: "Promotional Mix

18 Optimization Brand Level Model Results and ROI." In it, ZS conducted a "historical ROI and

19 marginal ROI analysis" of Endo's "pain brands." As explained in the presentation, at the time Endo

20 had been employing "a variety of marketing tactics to **drive prescribing volume** within the Pain

21 and UEO portfolios," and Endo "would like to better understand the effectiveness of each of these

22 tactics, and to **optimize marketing spending to drive efficiency**."⁶⁵⁵ Key questions ZS sought to

23 answer for its client were "how effective is each of Endo's marketing activities in terms of driving

24 prescription volume," and "what is the ROI for each marketing activity."⁶⁵⁶

25

26

27 _____

28 ⁶⁵⁵ ZS Presentation to Endo dated July 16, 2012, *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804-DAP, Doc. 2421-2, filed August 15, 2019 (N.D. OH).

⁶⁵⁶ *Id.*

870. ZS informed Endo plainly that, regarding its portfolio of pain medications, “[s]ales force detailing is the most impactful tactic, detailing accounts for 35-65 % of all sales and marketing impact.”⁶⁵⁷ With respect to Opana, Endo’s extended-release opioid tablet meant to compete with Purdue’s OxyContin, sales force detailing accounted for 11.7% of the contribution to annual sales and profitability among Endo’s sales tactics for Opana. In second place was co-pay cards, with 4.4%.⁶⁵⁸

% Contribution to annual sales and profitability by promotional tactic for each brand

Modeling time frame	Apr'11- Mar'12	Jan'11- Dec'11		Apr'11- Mar'12
Tactic	LIDODERM	OPANA	Voltaren Gel	FROVA
SF Detailing	● 8.3%	● 11.7%	● 5.9%	● 8.2%
NPP	● 3.1%	● 0.0%*	● 3.5%	● 7.5%
Samples	● 5.0%	N/A	● 2.1%	● 1.0%
Website	● 2.0%	● 2.1%	● 0.0%*	● 0.1%
Journals	● 0.5%	● 0.3%	N/A	N/A
Copay cards	● 0.4%	● 4.4%	● 2.7%	● 6.4%
Speaker programs	Not planned for 2012	● 0.2%	N/A	N/A
ALL TACTICS	19.3%	18.7%	13.2%	23.2%
CARRYOVER	77.1%	73.4%	70.8%	45.2%
OTHER FACTORS	3.6%	7.9%	15.0%	31.6%

● Positive mROI
 ● Approximately Breakeven mROI
 ● Negative mROI

* Not a statistically significant impact

11/2 ZS Associates

- 9 -

2012_07_16 Pharma Mix Optimization - ROI analysis v1

871. Opana ER constituted \$383 million in annual sales for Endo at the time of the ZS Associates analysis, good enough for the second highest selling Endo product analyzed by ZS. Of that \$383 million in sales, ZS determined that 19%, or \$72 million, is “driven by Sales and Marketing.”⁶⁵⁹ Furthermore, ZS informed Endo that “most of the promotional channels for Opana

⁶⁵⁷ *Id.*

⁶⁵⁸ *Id.*

⁶⁵⁹ *Id.*

1 ER have high ROI.” These “promotional channels” include marketing tactics such as copay cards,
2 website advertising, medical journal sponsorship, speaker programs, and detailing to prescribers.

3 872. The Opana marketing messages whose delivery ZS sought to optimize for Endo
4 conveyed misrepresentations regarding the dangers of the drug. For example, Endo maintained
5 until April 2012 the website opana.com, which stated, “[m]ost healthcare providers who treat
6 patients with pain agree that patients treated with prolonged opioid medicines usually do not
7 become addicted.” Upon information and belief, Endo did not conduct and does not possess data
8 or evidence to support that statement. Furthermore, the statement is misleading in that it suggests
9 that addiction is not a risk from taking extended-release opioids such as Opana.
10

11 873. Thus, ZS worked with Endo for at least a decade optimizing and implementing
12 misleading sales and marketing tactics, *including managing critical sales and marketing functions*
13 such as IC and CP. ZS’ successful performance of these tasks was critical to Endo’s efforts to
14 market Opana. Without ZS, Endo could not have achieved its opioid revenue goals.
15

16 874. On March 3, 2016, the New York Attorney General announced a settlement with
17 Endo to address the misleading marketing of Opana. The settlement required Endo “to cease all
18 misrepresentations regarding properties of Opana ER, to describe accurately the risk of addiction
19 to Opana ER, and to summarize studies regarding Opana ER on its website.”⁶⁶⁰ The settlement
20 further required Endo to create programs to prevent its sales representatives “from promoting
21 [Opana ER] to health care providers who may be involved in the abuse and illegal diversion of
22 opioids.”⁶⁶¹ Those safeguards were not in place under the sales and marketing program ZS designed
23 and helped Endo implement for years. Even at the time of the settlement announcement, ZS was
24 still working with Endo to shape and manage its Opana ER sales force.
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28 ⁶⁶⁰ See <https://ag.ny.gov/press-release/2016/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo>

⁶⁶¹ *Id.*

875. In May 2017, an advisory committee to the Food and Drug Administration recommended that Opana ER be withdrawn from the market due in part to the fact Opana ER could be “readily prepared for injection” (thereby bypassing the purportedly “abuse-deterrent” features of the formulation that Endo touted in its marketing) and was associated with outbreaks of HIV and a blood-clotting disorder known as thrombotic thrombocytopenic purpura (“TTP”). On June 8, 2017, the FDA adopted the committee’s recommendation.⁶⁶²

876. One month later, on July 6, 2017, Endo announced that it would agree to cease marketing and selling Opana ER altogether.

877. Just as was the case with Purdue, ZS was working with Endo on marketing its branded opioid product at the time that the company voluntarily ceased selling and marketing the drug in response to the dangers of continuing to market it.

4. Teva

878. Not to be left out, Teva Pharmaceuticals also relied on ZS [REDACTED]

879. Fentora is a fentanyl buccal tablet that is, “used for the treatment of breakthrough pain in cancer patients receiving opioid treatment and who have become tolerant to it.”⁶⁶⁴ It was approved by the Food and Drug Administration in 2006 for this limited use, but, as the FDA noted two years later, “off-label prescribing has, unfortunately, been widely practiced.”⁶⁶⁵

⁶⁶² “FDA requests removal of Opana ER for risks related to abuse,” June 8, 2017, *available at*: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>

⁶⁶³ See Teva Completes Acquisition of Cephalon, Fierce Pharma, October 11, 2011, *available at*: <https://www.fiercepharma.com/pharma/teva-completes-acquisition-of-cephalon>

⁶⁶⁴ See Fentanyl Buccal Tablets (marketed as Fentora) Information, *available at*: <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fentanyl-buccal-tablets-marketed-fentora-information>.

⁶⁶⁵ Memorandum from Bob A. Rappaport, MD to the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) dated April 26, 2008, Doc. 2231, *In re National Prescription Opiate Litigation*, No. 1:17-md-02804-DAP (N.D. Ohio) (filed August 13, 2019).

1 880. The Food and Drug Administration, in an April 26, 2008, memorandum discussing
 2 the possibility of an “expanded indication for Fentora for use in break-through pain in patients with
 3 chronic pain not caused by malignancy,” expressed concern about Fentora’s active ingredient,
 4 fentanyl, and the growing misuse of opioids despite the safeguards already put in place by the FDA:

5 Fentanyl has an extremely narrow therapeutic window, and even in opioid tolerant
 6 patients misuse and errors in dosing can result in significant morbidity and mortality.
 7 Exposure to minute quantities of fentanyl in opioid non-tolerant people, especially
 8 children and the elderly, can be lethal in minutes. If this product is to be indicated
 9 for increased widespread use, and if availability increases, a risk mitigation program
 10 that will attempt to prevent, monitor, and intervene, when necessary, will be
 11 essential. However, as already noted, *the current paradigms for risk management*
 12 *for potent opioid drug products may not have been fully successful.*⁶⁶⁶

13 881. Consistent with Dr. Rappaport’s concerns, on December 28, 2011, the FDA
 14 mandated a Risk Evaluation and Mitigation Strategy (“REMS”) for Fentora and other
 15 Transmucosal Immediate Release Fentanyl (“TIRF”).⁶⁶⁷

16 882. The following year, ZS determined that [REDACTED]
 17 [REDACTED]
 18 [REDACTED]
 19 [REDACTED]
 20 [REDACTED]

21 883. [REDACTED]
 22 [REDACTED]
 23 [REDACTED]
 24 [REDACTED]
 25 [REDACTED]

26 _____
 27 ⁶⁶⁶ Memorandum from Bob A. Rappaport, MD to the Anesthetic and Life Support Drugs Advisory Committee
 (ALSDAC) dated April 26, 2008, Doc. 2231, *In re National Prescription Opiate Litigation*, No. 1:17-md-02804-DAP
 (N.D. Ohio) (filed August 13, 2019) (emphasis added).

28 ⁶⁶⁷ See <https://www.fda.gov/drugs/information-drug-class/questions-and-answers-fda-approves-class-risk-evaluation-and-mitigation-strategy-rems-transmucosal>.

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884.

885. ZS was tasked not only with specific recommendations to [REDACTED] but such as [REDACTED] but in [REDACTED]

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886. In short, ZS was in charge of maximizing Teva's profit from selling fentanyl by optimizing and assisting in managing Teva's sales force.

⁶⁶⁸ See Corporate Integrity Agreement dated September 28, 2008, available at: <https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf>

⁶⁶⁹ See Corporate Integrity Agreement dated September 28, 2008, available at: <https://oig.hhs.gov/fraud/cia/agreements/cephalon.pdf>

⁶⁷⁰ The concept of "marketing mix" is one used by ZS to contextualize the product offerings it provides clients. "Marketing mix, simply stated is really just the set of promotional tactics that a product is using to sell and market itself. In the pharmaceutical industry, this can include a broad set of different kinds of promotional activities, things from very traditional tactics such as salesforce promotion or sampling, to more recent advances, things like co-pay cards, digital media," explained ZS' John Bienko. "Of course, the biggest question on anybody's mind is 'what is the financial impact I'm getting from these promotions, what's the bang for the buck?'" he added. See https://www.youtube.com/watch?v=V8mppVKr9_0

Obtaining an optimal marketing mix is an overarching goal of any client relationship ZS maintains. For example, in addition to its work for Teva, the concept of marketing mix was front of mind for ZS' work for Endo as well. See *supra*, Paragraph 869. "Optimal," in this context, means most profitable.

891. The only thing that matters is the bottom dollar, and the bottom dollar is driven by the volume of goods sold.

892. Publicis understands this. In Publicis' own words:⁶⁷¹

In healthcare, performance cannot be measured in clicks or impressions or even office visits. Our only KPI is outcomes — business outcomes and patient outcomes. Our best-in-class outcomes analytics methodology enables us **to see real ROI**. But sound, evidence-based measurement isn't just about **proving** ROI — it's also about **optimizing** for it. With the best data-driven analytics team in healthcare media, we're able to achieve performance that outclasses the field — with **ROI four times greater than our closest competitor**.

893. Publicis' actions for its clients provide numerous real-world instances of this myopic focus on money. For example, in April 2013, Publicis implemented an email marketing campaign offering downloadable OxyContin "Savings Cards," which Publicis knew was a tactic for patient retention, or, keeping patients on OxyContin for longer periods of time. Again, Publicis couched the campaign's worth in terms of "return on investment" for Purdue. While Publicis charged Purdue \$47k for the campaign, Publicis and Purdue later assessed the incremental impact of the campaign to have been an additional 67,000 OxyContin prescriptions by April 2014.

894. Despite that apparent success, Publicis and Purdue wanted more. Notes from an internal Publicis meeting held four months later, in August of 2014, to discuss work on the Purdue account make it plain. Patient retention and return on investment remained top of mind:

- Patient Retention – "How do we get a 2:1 return on this?"
 - What is a patient worth?
 - What is a monthly script worth?
 - What is the value of getting just *one* more refill?
 - Isn't brand retention so much as overall portfolio retention
- In the beginning, Purdue got reprimanded for going after patients too aggressively
- Hence the focus is more company versus brand oriented; feels more altruistic
- Determine at the patient level what they need for their condition
- Does portfolio retention need to be veiled in a patient engagement program?

⁶⁷¹ See <https://www.publicishealthmedia.com/our-approach/> (emphasis added).

1 “What is a patient worth?... How do we get a 2:1 return on this?... getting just *one* more
2 refill.” Internally, Publicis was direct in describing what matters.

3 895. The meeting was held to discuss additional projects to be performed in the realm of
4 “patient retention” for Purdue. “Patient retention” for Purdue has all of the same benefits as “client
5 retention” does for Publicis. In other words, Publicis was working to assure people stayed on their
6 OxyContin prescriptions and never quit. Given the unpleasantness of that goal, Publicis wondered,
7 “Does portfolio retention need to be veiled in a patient engagement program?”⁶⁷²

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9 896. Likewise, ROI was paramount in Publicis’ decision to engage Practice Fusion on
10 the Purdue account. In a July 18, 2014, internal email, Publicis’ John Dwyer asked a colleague,
11 “Can you find out if they [Practice Fusion] have any kind of ROI of Rx impact metrics around these
12 that they can share?”

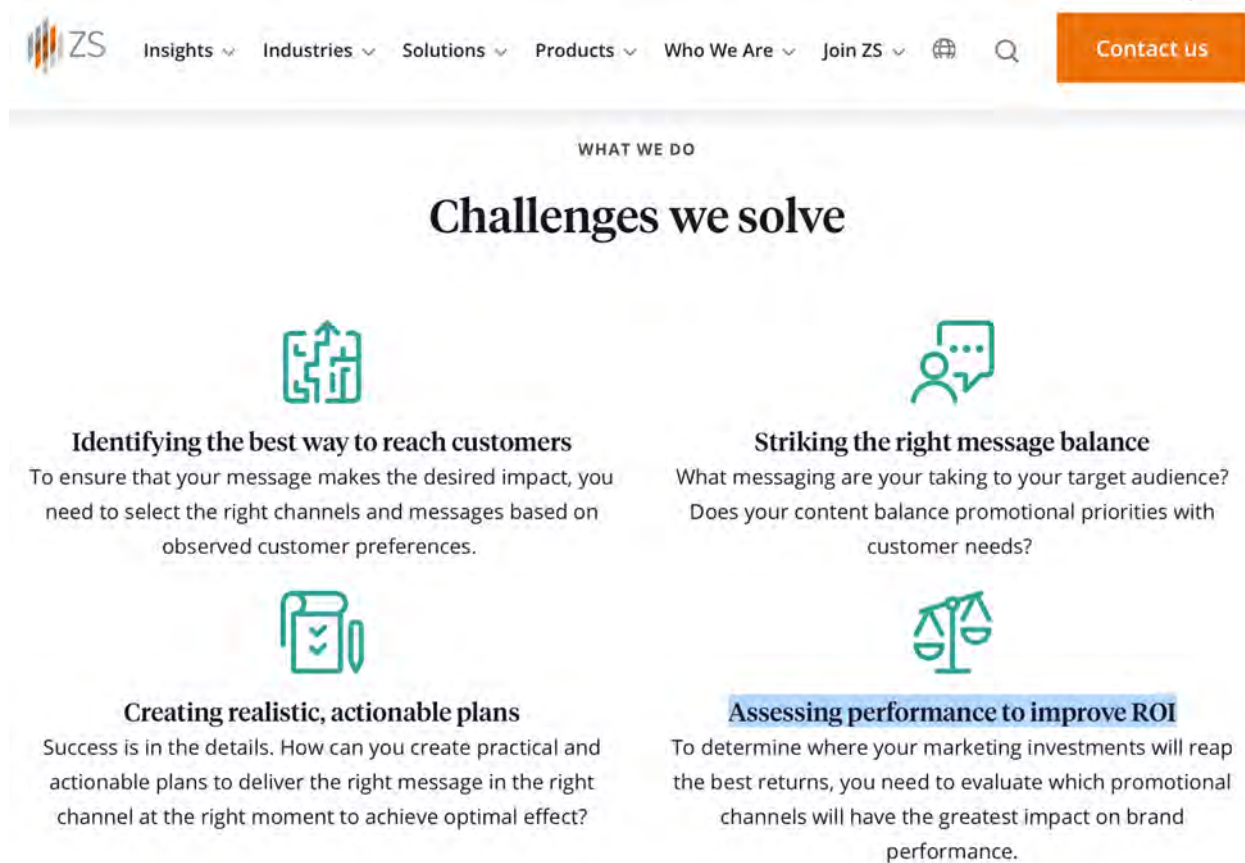
13
14 897. ROI was king, but Publicis knew you couldn’t just *say* that. In October 2014,
15 Publicis was working with Purdue to devise an “Outward Facing Strategy,” whereby Publicis would
16 help Purdue present itself as a responsible corporate citizen to the world. Publicis noted that the
17 current corporate tagline of “profitable growth” was not “outward facing” and was instead “strictly
18 for internal use.”

19 898. Describing the bottom line regarding the services ZS provides its clients, ZS
20 Principal John Bienko stated, “Of course, the biggest question on anybody’s mind is ‘what is the
21 financial impact I’m getting from these promotions, what’s the bang for the buck?’”⁶⁷³

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27 ⁶⁷² For a discussion of why Publicis might wish to “veil” its retention goals in the guise of “patient engagement,” *see*
supra., Section IV(e)(iii)(c).

28 ⁶⁷³ *See* ZS Associates, “Marketing mix strategy: why it’s so important for pharmaceutical marketing,” available at:
https://www.youtube.com/watch?v=V8mppVKr9_0

899. ZS' *raison d'être* is maximizing return on investment for all sales and marketing spending for a pharmaceutical manufacturer. ZS was not shy about couching its entire product line to pharmaceutical manufacturer clients in terms of ROI⁶⁷⁴:



900. ROI is the basis upon which ZS advertises and sells its services to pharmaceutical companies, and it is the principal reason that a pharmaceutical company hires ZS in the first place. As established herein, ZS couched substantially *all* of its proposals to work for opioid manufacturers in terms of how much money they will make by doing what ZS recommends.

901. This myopic focus on the bottom line, when applied to controlled substances known to be addictive, would have predictable consequences.

ii. **McKinsey Publicis Knew; Practice Fusion Knew; ZS Knew; Everyone Knew**

⁶⁷⁴ See <https://www.zs.com/solutions/marketing/promotions-and-marketing-mix>

902. As described above, the problem with broadly and aggressively marketing addictive opioids was apparent from the start: controlled substances are *controlled* precisely because they should not be sold to maximize volume and profits. Defendants actively disregarded this plain fact, repeatedly, and for decades.

1. McKinsey Knew

903. The deceptive marketing strategies McKinsey developed and helped to implement were successful. Its granular growth tactics, myopically focused on increased revenues for its clients, substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and as of 2016, 20% of office visits for non-cancer pain included the prescription of an opioid.⁶⁷⁵

904. The dangers of opioids were known to McKinsey at the time it engaged in the misconduct described in this Complaint. The addictive potential of opioids and the need for control and restraint in their use was internally understood, as was the likelihood of large-scale opioid addiction, abuse, overdoses, illness, and early death resulting from sharply increased use.

905. McKinsey also performed its own research in evaluating the anticipated effects of Project Turbocharge. An April 2014 implementation update observed an increase in sales calls, as well as that “OxyContin [health care providers] with increased calls consistently outperform HCPs with decreasing or no change in call frequency.”

906. McKinsey continued working with Purdue long after the severity of the opioid crisis was well known. McKinsey knew that high dose OxyContin prescriptions carried a serious risk of overdose. In 2017, over half of Purdue's opioids prescriptions exceeded the ninety mg morphine

⁶⁷⁵ Deborah Dowell, Tamara M. Haegerich, and Roger Choi, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, CDC (March 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

1 equivalence threshold a day—the recommended maximal dose per the 2016 CDC Guideline for
2 Prescribing Opioids for Chronic Pain.

3 907. Purdue’s 2007 guilty plea put McKinsey on notice of Purdue’s misconduct. By that
4 time, McKinsey had access to public information indicating that OxyContin and other opioids pose
5 significant risk of addiction and misuse.
6

7 908. McKinsey was well aware of the risks of OxyContin based on its extensive
8 experience in the pharmaceutical industry, close collaboration with Purdue, and participation in the
9 regulatory submissions for reformulated OxyContin.⁶⁷⁶

10 909. The first bullet point of Purdue’s 2007 “Observations and Activities Requiring an
11 [Abuse, Diversion, and Detection] Report” was “[a]n apparent pattern of an excessive number of
12 patients for the practice type[.]”⁶⁷⁷ Thus, McKinsey knew or should have known that there was a
13 higher risk of abuse and diversion among high-volume prescribers.
14

15 910. What is more, on September 13, 2013 McKinsey briefed Purdue on the ongoing
16 concerns regarding OxyContin addiction and diversion among prescribers:
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27 ⁶⁷⁶ McKinsey [REDACTED]

28 [REDACTED] McK-MAAG-0118819 (email chain).

⁶⁷⁷ PPLPC010000033944.

Findings on messaging and positioning

PRELIMINARY

- Opioids overall are still viewed as effective and necessary class of painkillers, though side effects and addiction are concerns
- Key themes from prescriber interviews on abuse deterrents include:
 - Prescriber awareness of abuse deterrence and label change is mixed
 - Opinions on impact/efficacy of abuse deterrence vary
 - Most prescribers are concerned about abuse, but attempt to establish measures to protect themselves
 - Concerns remain that technology does not address oral abuse
 - Less informed prescribers ask for additional information and education around abuse deterrent formulations
- Existing market research suggests that most physicians do not feel that reformulation positively impacts their prescribing behavior, and that diversion, abuse and regulatory concerns continue to weigh on prescribers

McKinsey & Company | 27

911. In a PowerPoint slide entitled “Findings on messaging and positioning,” part of a presentation to Purdue entitled “OxyContin growth opportunities: Phase 1 Final Report: Diagnostic,” McKinsey noted that “most prescribers are concerned about abuse,” and that “most physicians do not feel that [OxyContin] reformulation positively impacts their prescribing behavior, and that diversion, abuse and regulatory concerns continue to weigh on prescribers.”

912. In an August 2017 presentation, McKinsey recognized that the opioid epidemic was “triggered, in large part, by a massive increase in prescribed opioids in the early 2000’s.”

913. McKinsey’s presentations to Purdue included extensive discussion of doctors’ concerns about opioid misuse and side effects, demonstrating McKinsey’s awareness of the dangers of opioids. Rather than working to limit these disastrous effects, McKinsey treated doctors’ misgivings as obstacles to confront with new messaging.

914. Indeed, one reason that *Purdue* had knowledge that their own products were addictive and dangerous is because McKinsey told them.

1 915. If McKinsey was not aware of the adverse consequences of OxyContin, the drug it
2 was paid to sell, such ignorance could not survive the granular reality of its relationship with
3 Purdue. For example, in June 2009, McKinsey worked to “counter the emotional messages from
4 mothers with teenagers that overdosed on OxyContin.”⁶⁷⁸

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6 916. Within a few years of countering these emotional messages, McKinsey even
7 developed a method to identify geographic hot spots of OxyContin abuse and diversion. Once
8 developed, however, McKinsey simply never used it to decrease these harms.

9 917. Paul Coplan [REDACTED]
10 [REDACTED]
11 [REDACTED]
12

13 918. In deposition testimony in prior opioid-related litigation, Coplan was asked, “While
14 you were at Purdue, did Purdue make an effort to identify hot spots for opioid abuse and addiction
15 or not?”⁶⁸⁰

16 919. [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
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21 920. [REDACTED]
22 [REDACTED]
23 [REDACTED]
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27 ⁶⁷⁸ PDD8901645845.

28 ⁶⁷⁹ Paul M. Coplan 1/18/19 Dep. Tr. At 16:18 -17:17.

⁶⁸⁰ *Id.* at 355:10.

⁶⁸¹ *Id.* at 355:14–356:11.

⁶⁸² *Id.* at 357:8-16.

1 [REDACTED]

2 [REDACTED]⁶⁸³

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4 921. Instead, McKinsey focused on increasing opioid sales for its clients, despite

5 knowing the harmful consequences of doing so. In yet another indication that OxyContin sales

6 should not be turbocharged: during McKinsey's work for Purdue, Purdue was unable to purchase

7 product liability insurance to cover its practice of selling OxyContin.

8 922. The basic premise of McKinsey's work put it on notice of the harmful consequences

9 that would ensure. It was tasked with advising a monoline manufacturer of opioids about sales and

10 marketing practices for its addictive products while that manufacturer was bound by a five-year

11 Corporate Integrity Agreement covering the very same opioid sales and marketing practices. In

12 2012, OxyContin accounted for 94% of Purdue's revenue.⁶⁸⁴ As late as 2018, it remained 84% of

13 Purdue's revenue.⁶⁸⁵ According to the U.S. Department of Justice, "[f]rom 2010 to 2018, Purdue's

14 profits were almost entirely driven by its success in selling OxyContin."⁶⁸⁶ In 2015 alone, it

15 obtained \$3 billion in annual opioid sales—a four-fold increase from its 2006 sales of \$800 million.

16

17 923. McKinsey's mandate was to increase Purdue's opioid sales during a time when

18 Purdue was obligated to restrict its previous marketing strategies because those strategies had

19 caused the *overprescribing of opioids* and the inevitable consequences thereof. McKinsey's job

20 was to counter the intended results of the Corporate Integrity Agreement; to devise strategies to sell

21 as many pills as conceivably possible. Under McKinsey's tutelage, Purdue's growth continued its

22 upward trajectory unabated, the Corporate Integrity Agreement notwithstanding.

23

24

25 2. Publicis Knew

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27 ⁶⁸³ *Id.* at 357:22–358:6.

28 ⁶⁸⁴ Gerald Posner, *Pharma*, pg. 524 (Simon & Schuster 2020).

⁶⁸⁵ *Id.*

⁶⁸⁶ <https://www.justice.gov/opa/press-release/file/1329571/download>

1 924. Like Publicis Touchpoint Solutions' work with Orexo, Publicis's Saatchi and
2 Saatchi also worked the other end of the epidemic. In 2017, it sponsored New York Festivals Global
3 Awards Young Globals competition, where the winning team would win an internship opportunity.
4 The Young Globals is "the only college/portfolio competition for healthcare advertising."⁶⁸⁷ The
5 competition called for "creative challenge briefs" to be submitted "for the (fictional) National
6 Opioid Addiction Prevention Council and invites student entrants to develop a unique and
7 compelling multi-channel experience (print, social media, digital, etc.) for their project Push Back
8 on Opioid Abuse," in order to "raise awareness about opioid addiction."⁶⁸⁸

10 925. The same year, the President of the United States declared the opioid crisis a
11 National Health Emergency.

12 926. Of course, everyone was aware of the problem long before 2017. On June 11, 2014,
13 Publicis' John Dwyer was informed that the DEA believed "an oversupply of painkillers is fueling
14 the black market for both prescription opioids and heroin," and furthermore that 668 individuals in
15 the State of Massachusetts alone died of opioid overdoses in a single year (2012). In an internal
16 Publicis email, Dwyer conceded, "in the opioid market there are so many other factors to consider
17 than just 'how can we increase sales of our product?'"

18 927. Dwyer's expressed concern about "other factors to consider" when selling opioids
19 is belied by the reality of Publicis actual work with Purdue, where "increasing sales of our product"
20 was *literally* the goal Publicis were hired to pursue.⁶⁸⁹ When the rubber meets the road, ROI is the
21 only metric that matters.

22 928. Dwyer himself was in a unique position of knowledge. As a Publicis colleague told
23 him in July 2016, "I doubt there's a marketer that knows the opioid marketplace like you do. You
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27 ⁶⁸⁷ See <https://www.lbbonline.com/news/new-york-festivals-young-global-awards-open-for-entries>

28 ⁶⁸⁸ See <https://www.lbbonline.com/news/new-york-festivals-young-global-awards-open-for-entries>

⁶⁸⁹ See PPLPC018000873870 ([REDACTED])

1 are speaking from a very secure place of knowledge in terms of RX targeting and who is driving
2 RXs.”

3 929. That knowledge was placed front and center in Publicis’ pitch to the non-profit
4 Partnership to End Addiction for work on the website drugfree.org. In the pitch, Dwyer and
5 Razorfish Health Vice President Karl Tiedemann highlighted Publicis’ deep knowledge of the
6 opioid marketplace, and described its work for Purdue:
7

8 We’ve been immersed in the evolving national opioid medication dialogue going on
9 between pharma companies, the government and FDA, the media, and the public
10 via **inside access as a trusted and informed consulting partner**... We’ve been
11 ingrained in the evolution of these issues for 6 years as other companies have come
12 and gone; monitoring the progress made with HCP’s and patients. (emphasis added).

13 930. The detailed scope of Publicis’ involvement in the opioid industry that Tiedemann
14 and Dwyer set forth in their pitch to *a nonprofit combatting opioid addiction* is remarkable. On
15 March 1, 2016, Dwyer jotted down fifteen reasons why Publicis was “the indisputably most
16 knowledgeable and most experienced agency to help with drugfree.org.”
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To: Karl Tiedemann[karl.tiedemann@razorfishhealth.com]; Scott Reese[scott.reese@razorfishhealth.com]
 From: John Dwyer
 Sent: Tue 3/1/2016 12:02:17 AM (UTC-05:00)
 Subject: RFH experience for Drugfree.org

Some notes I jotted down summarizing our relevant experience in this area since 2010 that positions us as the indisputably most knowledgeable and most experienced agency to help with drugfree.org.

1. Worked with Purdue Pharma since Feb 2010
2. Not just on the promotion of their opioid medications OxyContin, Butrans, Targiniq and Hysingla ER
3. Worked on unbranded pain education program and website Partners Against Pain; rebranded, reinvented entire site twice including content and resources for HCPs, patients and caregivers
4. Worked on company branding and website PurduePharma.com in 2011 and again in 2015
5. Worked on Purdue's OxyContin REMS program materials for soft re-launch/re-brand of OxyContin for reformulation in Sept 2010
6. Agency selected to lead work creating branding and site content development for multi-pharma company-sponsored class wide ER and LA opioid REMS program in 2012
7. Developed strategy, messaging and brand campaign for OADP (opioids with abuse-deterrent properties) unbranded campaign used on teamagainstopioidabuse.com; site features content created for 7 stakeholder groups: Physicians; Patients/caregivers; Pharmacists; Payors; Parents and communities; Police and law enforcement; Pharma companies
8. Collaborated for the above with various departments outside of product Marketing: Public Affairs; Patient Advocacy; Promotional Med Ed; and programs Safeguard My Meds; Rx Safety Matters; In the Face of Pain; RxPatrol
9. Contributed to promotion and dissemination of all of the above via multi-channel promotion including websites, email campaigns, banner ads, convention materials, print ads, media buying, SEM (paid search), and SEO
10. Created the first oxycontin.com publicly accessible website including a Patient site with Patient content and materials
11. Participated in dozens of market research projects with hundreds of HCPs, payers, pharmacists and patients over 6 years
12. Attended pain and pain medicine conferences since 2010
13. Attended Advisory Boards with PCPs and multiple pain treating specialties
14. We've been immersed in the evolving national opioid medication dialogue going on between pharma companies, the government and FDA, the media, and the public via inside access as a trusted and informed consulting partner
15. We've been ingrained in the evolution of these issues for 6 years as other companies have come and gone; monitoring the progress made with HCPs and patients

John Dwyer
 SVP, Group Account Director
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 P 212.771.5428 M 917.797.9317

3. Practice Fusion Knew

931. In April 2014, an internal email between Practice Fusion employees counseled that “indicating that Purdue influenced clinical decisions through sponsored money has legal implications versus a marketing program where a banner can be displayed and influence a prescribing behavior.”⁶⁹⁰

932. Practice Fusion knew which side of the line their conduct fell on. In a March 23, 2015, internal email, Practice Fusion discussed pitching CDS alerts to Purdue, and stated that Purdue “has communicated that the average dosage of OxyContin is declining,” because prescribers

⁶⁹⁰ Practice Fusion Information at Para. 27.

1 are “hesitant about using high dosages to combat pain for a variety of reasons, mostly, political
2 pressure.” Because of this “pressure,” Purdue might use Practice Fusion to boost prescriptions...
3 “Purdue is toying with the idea of using Pain Assessment tools with the provider at every visit and
4 before every RX.”

5
6 933. In September 2015, a Practice Fusion employee advised a Practice Fusion colleague
7 in an internal email, “I understand that the Purdue proposal has shifted to a commercial focus and
8 that marketing folks were in the room instead of outcomes... there are several things incorrect with
9 this presentation/proposal from pricing to products. Please do not share. Just be aware...”⁶⁹¹ That
10 same month, another Practice Fusion employee wrote in a separate internal email describing a
11 meeting with Purdue: “[W]e were talking to product managers, and they could care less about RWE
12 [real world evidence]. For them, this was all about marketing.”⁶⁹²

13
14 934. Practice Fusion knew that Purdue was only concerned about increasing
15 prescriptions. On May 11, 2016, a Practice Fusion employee observed that in a meeting with Purdue
16 to discuss the development of the CDS alert, he kept “hearing the client [Purdue] revert back to ‘Rx
17 lift’ as the primary objective of the program, this came up in the kickoff meeting and again during
18 last week’s meeting.” Repeatedly, Purdue made it clear to Practice Fusion what mattered.

19
20 935. Practice Fusion knew that even *Purdue* had legal concerns about the CDS alerts
21 program. Purdue asked that Practice Fusion provide an update on the results of the CDS Program,
22 including whether “the CDS alerts change prescribing behavior” with respect to EROS. The
23 meeting between Practice Fusion and Purdue occurred on December 14, 2016. A Purdue attorney
24 at the meeting expressed reservations about the CDS program and noted that the program had not
25 received appropriate legal review within Purdue.⁶⁹³

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28 ⁶⁹¹ Practice Fusion Information at Para. 58.

⁶⁹² Practice Fusion Information at Para. 60

⁶⁹³ Practice Fusion Information at Para. 110.

1 936. A post-hoc legal review of the CDS alert program was conducted by Purdue with
 2 Practice Fusion's input in December 2016 and January 2017. Despite the legal review, none of the
 3 conduct that led to Purdue's subsequent guilty plea and Practice Fusion's deferred prosecution
 4 agreement was altered or paused. The conduct continued until 2019.

6 4. **ZS Knew**

7 937. ZS was in a truly unique position, given its dominance of pharmaceutical sales and
 8 marketing consulting, practically all industry participants were its clients. While advising multiple
 9 industry participants regarding the sales of competing products (OxyContin and Opana, for
 10 instance) **at the same time**, ZS was in a position to know confidential information and trade secrets
 11 of these clients. Indeed, the contracts between ZS and its clients specify that ZS will have access to
 12 the clients' confidential and proprietary information. Given the nature of ZS' work, it cannot
 13 adequately perform its function for clients without that access.

14 938. ZS' clients were repeatedly subjected to enforcement actions for their work selling
 15 opioids both before and during the pendency of the ZS client relationship. For instance, in addition
 16 to its 2007 guilty plea with the United States Department of Justice ("DOJ"), Purdue Pharma settled
 17 with the State of Kentucky in 2015 for \$24 million.⁶⁹⁴ The settlement concerned similar conduct as
 18 the 2007 guilty plea, including the sales and marketing of Purdue's opioids. ZS was involved in
 19 this work.

20 939. Two years later, on July 11, 2017, another ZS client settled charges that it failed to
 21 report suspicious orders of opioids and for various recordkeeping violations. In this case,
 22 Mallinckrodt's failure to comply with DEA regulations regarding the sales of opioids resulted in a
 23 \$35 million payment to the DOJ.⁶⁹⁵

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 27 ⁶⁹⁴ See the December 22, 2015, settlement between the Commonwealth of Kentucky and Purdue Pharma Inc., available
 at https://ag.ky.gov/pdf_news/purduepharmaoxycontin.pdf.

28 ⁶⁹⁵ See <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

1 940. The settlement agreement related to conduct between 2008 and 2011, during which
2 time ZS was advising Mallinckrodt.

3 941. Because of these client relationships, ZS was in a unique position to know how the
4 entire industry's opioid sales and marketing tactics were playing out, both in terms of return on
5 investment for their individual clients, as well as overall market trends such as the rise of the opioid
6 crisis. Endo may not have known the specifics of competitor Purdue's marketing efforts for
7 OxyContin, just as Purdue may not have known the specifics of Endo's Opana plan. But ZS knew
8 both, as well as what Teva and Mallinckrodt were doing with their own branded opioid sales and
9 marketing efforts *in real time*.
10

11 5. Everyone Knew

12 942. The evidence of a direct link between increased opioids marketing and sales and
13 increased opioid abuse was everywhere. A 2007 study found "a very strong correlation between
14 therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."⁶⁹⁶
15 McKinsey evidently understands this. In a September 2016 online article, McKinsey asserts that
16 "[t]here is no doubt that more consistent use of best practices – across geographic areas, institutions,
17 and clinicians – would provide tremendous help in combating the crisis" and describes certain
18 examples of such practices as "successful in reducing prescribing."⁶⁹⁷
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20 943. There is a "parallel relationship between the availability of prescription opioid
21 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
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26 ⁶⁹⁶ Theodore J Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural,*
27 *Suburban, and Urban Locations in the United States*, 16.8 *Pharmacoepidemiology and Drug Safety*, 827-40 (2007),
available at <https://onlinelibrary.wiley.com/doi/10.1002/pds.1452>.

28 ⁶⁹⁷<https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic>

1 associated adverse outcomes.”⁶⁹⁸ The opioid epidemic is “directly related to the increasingly
2 widespread misuse of powerful opioid pain medications.”⁶⁹⁹

3 944. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has
4 quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving
5 opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the
6 CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to
7 reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”⁷⁰⁰

8 945. Compounding the harm from deceptive marketing, Defendants worked with Purdue
9 to continue and grow the opioid sales of prescribers that raised red flags of diversion, despite
10 Purdue’s legal obligations to report and halt supply. In doing so, it enabled an oversupply of opioids,
11 which allows non-patients to become exposed to opioids, and facilitates access to opioids for both
12 patients who could no longer access or afford prescription opioids and addicts struggling with
13 relapse.

14 946. Most of the illicit use originates from prescribed opioids. It has been estimated that
15 60% of the opioids that are abused come, directly or indirectly, through physicians’ prescriptions.

16 947. As McKinsey itself has recognized in citing a study reaching this conclusion,
17 roughly 80% of heroin users previously used prescription opioids.⁷⁰¹ As many as one in four
18 patients who receive prescription opioids long-term for chronic pain in primary care settings
19 struggles with addiction. And the link between prescription narcotic painkiller abuse and
20 subsequent and/or simultaneous heroin abuse continues to grow.

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26 ⁶⁹⁸ Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).

27 ⁶⁹⁹ Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse*, New Engl. J. Med. (Apr. 14, 2016).

28 ⁷⁰⁰ CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *et al.* “Increases in drug and opioid overdose deaths – United States, 2000–2014.” *American Journal of Transplantation* 16.4 (2016): 1323-1327.

⁷⁰¹ <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic>

1 948. In fact, people who are addicted to prescription opioid painkillers are 40 times more
2 likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the
3 strongest risk factor for heroin addiction. A more recent, and even more deadly problem stemming
4 from the prescription opioid epidemic involves fentanyl, a powerful opioid prescribed for cancer
5 pain or in hospital settings that, in synthetic form, has made its way into Plaintiffs' communities.

6 949. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin
7 and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary medicine to
8 sedate large wild animals such as elephants, and has been researched as a chemical weapon. A dose
9 the size of a grain of salt can rapidly lead to deadly overdose in humans.

10 950. No demographic is untouched by this epidemic. Nationally, one in five deaths
11 among younger adults in 2016 involved opioids, according to one study. And deaths involving both
12 prescription and illicit opioids have risen sharply, nearly doubling since 2009.

13 951. Opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25%
14 involved heroin. According to the CDC, between 1999 and 2015, more than 183,000 people died
15 in the United States from prescription-related overdoses.

16 952. Rising opioid use and abuse have negative social and economic consequences far
17 beyond overdoses in other respects as well. According to a recent analysis by a Princeton University
18 economist, approximately one out of every three working age men who are not in the labor force
19 take daily prescription pain medication. The same research finds that opioid prescribing alone
20 accounts for 20% of the overall decline in the labor force participation for this group from 2014 to
21 2016, and 25% of the smaller decline in labor force participation among women. Many of those
22 taking painkillers still said they experienced pain daily.

23 953. In 2009, Dr. Van Zee identified the *precise tactics* that Defendants deployed for all
24 of their opioid clients, including Purdue, as a source of OxyContin misuse and abuse, and suggested
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1 that regulation may be appropriate to curtail the use of the marketing tactics deployed by
 2 Defendants: “The use of prescriber profiling data to target high-opioid prescribers – coupled with
 3 very lucrative incentives for sales representatives – would seem to fuel increased prescribing by
 4 some physicians – perhaps the most liberal prescribers of opioids and, in some cases, the least
 5 discriminate.”⁷⁰²

7 954. In time, additional evidence mounted supporting the conclusion that Defendants’
 8 sales and marketing tactics were demonstrably exacerbating the nationwide opioid crisis. One way
 9 of demonstrating the link between aggressive sales and marketing of opioids and worsened
 10 mortality outcomes arose out of a quirk of Purdue’s own marketing tactics.

11 955. In 1996, when OxyContin was introduced, five states – California⁷⁰³, Idaho, Illinois,
 12 New York and Texas – maintained “triplicate” programs that required prescribers of Schedule II
 13 controlled substances to fill out prescriptions in triplicate.⁷⁰⁴ One of the triplicate copies would then
 14 be filed with the state agency in charge of maintaining a prescription database intended to monitor
 15 diversion and other potential issues relating to the over-dissemination of Schedule II narcotics.
 16 These triplicate programs were precursors to modern prescription drug monitoring programs that
 17 have been instituted in nearly every state in response to the opioid crisis.

19 956. Purdue recognized that the requirement to submit records of controlled substance
 20 prescriptions to a governmental database chilled prescribers’ willingness to prescribe medications
 21 subject to the constraints of the triplicate programs. Because Purdue viewed these triplicate
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 25 ⁷⁰² Art Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99 AM.
 26 J. PUB. HEALTH 221, 221, 224 (Feb. 2009), available at:
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf>.

27 ⁷⁰³ California was the first state to implement a triplicate program in response to concerns about the diversion of opium-
 28 based pharmaceuticals. The year was **1939**. See Abby E. Alpert, William N. Evans, Ethan M.J. Lieber, and David
 Powell, *Origins of the Opioid Crisis and its Enduring Impacts*, NBER Working Paper No. 26500, November 2019,
 available at: <https://www.nber.org/papers/w26500>; See also, *supra.*, fn. 1.

⁷⁰⁴ Patrick Radden Keefe, *Empire of Pain*, Pg. 407.

requirements as an overly burdensome hindrance on prescribing, the company chose to focus its marketing efforts in other states that did not impose these constraints.

957. This resource-allocation decision by Purdue to focus more marketing efforts in states with fewer regulations regarding the prescribing of controlled substances provided a way to test whether *marketing* of OxyContin, by itself, was a cause of not only increased overdose rates for OxyContin, but of *all* opioid-related overdoses, *including* those involving illicit opioids such as heroin and fentanyl.

958. The results were stark. In 2019, economists from the University of Pennsylvania, Notre Dame, and the RAND Corporation analyzed the disparate outcomes in overall opioid overdose mortality experienced in the triplicate states, where Purdue did not focus its marketing efforts, and non-triplicate states where Purdue did focus those efforts.⁷⁰⁵

959. The economists found that “OxyContin distribution was about 50% lower in ‘triplicate states’ in the years after the launch. While triplicate states had higher rates of overdose deaths prior to 1996, this relationship flipped shortly after the launch [of OxyContin] and triplicate states saw substantially slower growth in overdose deaths, continuing even twenty years after OxyContin’s introduction. **Our results show that the introduction and marketing of OxyContin explain a substantial share of overdose deaths over the last two decades.**”⁷⁰⁶

960. A 2017 *Journal of American Medical Association* study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.⁷⁰⁷ The changes in prescribing behavior appeared

⁷⁰⁵ Abby E. Alpert, William N. Evans, Ethan M.J. Lieber, and David Powell, *Origins of the Opioid Crisis and its Enduring Impacts*, NBER Working Paper No. 26500, November 2019, available at: <https://www.nber.org/papers/w26500>

⁷⁰⁶ *Id.* (emphasis added).

⁷⁰⁷ Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass’n 1785 (2017).

strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

961. Separately, a recent *Journal of American Medical Association* study analyzed the Centers for Medicare and Medicaid Services' Open Payments database regarding pharmaceutical company marketing efforts towards doctors, as well as CDC data on prescription opioid overdose deaths and prescribing rates, in order to assess whether pharmaceutical marketing of opioids to physicians affected the rate of prescription opioid overdose deaths. Notably, the study analyzed these marketing practices beginning August 1, 2013, and ending December 31, 2015.⁷⁰⁸

962. Those dates are significant, as the study captures the same timeframe that McKinsey's Project Turbocharge, re-christened *E2E*, was implemented.

963. The study noted "physician prescribers are the most frequent source of prescription opioids for individuals who use opioids nonmedically."⁷⁰⁹

964. The study found that "increased county-level opioid marketing was associated with elevated overdose mortality 1 year later, an association mediated by opioid prescribing rates; per capita, **the number of marketing interactions with physicians demonstrated a stronger association with mortality** than the dollar value of marketing."⁷¹⁰

⁷⁰⁸ Scott E. Hadland *et. al.*, *Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality from Opioid-Related Overdoses*, JAMA Network, January 18, 2019, available at: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720914>.

⁷⁰⁹ *Id.*

⁷¹⁰ *Id.* (emphasis added)

1 965. Referring to the types of sales and marketing tactics Publicis provided to its clients,
2 and helped them implement, the authors concluded, “amid a worsening opioid crisis, our results
3 suggest that industry marketing to physicians may run counter to current efforts to curb excessive
4 opioid prescribing.”⁷¹¹

5 966. The authors’ proposed solution was plain simple, and echoed Dr. Van Zee’s
6 congressional testimony from 2002: “Pharmaceutical companies might also consider, as one
7 manufacturer recently did, **voluntarily ceasing marketing opioid products directly to**
8 **physicians.**”⁷¹²

9 967. Incredibly, in an August 7, 2016, presentation to Purdue regarding their “Corporate
10 Identity Transformation,” Publicis offered, as one strategy *option* to be *considered* among others,
11 voluntarily ceasing to market opioids in order to “fully embrace a deeper-held responsibility for
12 progress in pain and keeping people safe.” The pain franchise could be placed “on probation.” It
13 would be a “bold commitment.”
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28 ⁷¹¹ *Id.*

⁷¹² *Id.*

PUT THE PAIN FRANCHISE "ON PROBATION"
ACTIONS THAT DEMONSTRATE A BOLD COMMITMENT

Take clear, bold, and direct actions at the corporate level to show the public that Purdue is willing to compromise its own business in order to fully embrace a deeper-held responsibility for progress in pain and keeping people safe

<p>Shut Down the Sales Force (Shift to MSL Model)</p> <p>While the sales force is incentivized to sell products, Purdue can commit to more responsibly serving physicians by employing only an expanded team of Medical Science Liaisons (MSLs) for managing 1-to-1 personal interactions with HCPs.</p>	<p>Achieve Full HCP Compliance with ER-LA REMS Program</p> <p>Aspire to regulate who is qualified to prescribe opioids. Purdue leads the effort working with FDA and other pharma companies to up its commitment to getting HCPs REMS-compliant if they're going to prescribe opioid pain meds.</p>	<p>Get Every Patient Off Purdue's Medications</p> <p>Boldly commit to the goal of getting every patient off therapy; employ systems and strategies across all brands to help HCPs and Patients better manage their pain regimen and plan for the eventual discontinuation of pain therapy.</p>
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968. Defendants' role in the opioid industry was central. Given its overlapping engagements with multiple opioid manufacturers regarding the sales of competing products **at the same time**, Defendants were in a position to know the intricacies of the sales and marketing tactics of competing opioid sellers, including confidential information and trade secrets of these clients. And Publicis served as matchmaker to Defendant Practice Fusion, ushering it in to service opioid accounts like Purdue's that Publicis already controlled.

969. All the while, Defendants' clients were repeatedly subjected to enforcement actions for their work selling opioids both before and during the pendency of Defendants' client relationships. For instance, after its 2007 guilty plea with the United States Department of Justice ("DOJ"), Purdue Pharma settled with the State of Kentucky in 2015 for \$24 million.⁷¹³ The

⁷¹³ See the December 22, 2015, settlement between the Commonwealth of Kentucky and Purdue Pharma Inc., available at https://ag.ky.gov/pdf_news/purduepharmaoxycontin.pdf.

1 settlement concerned similar conduct as the 2007 guilty plea, including the sales and marketing of
2 Purdue's opioids. Defendants were all active participants in and contributors to this conduct.

3 970. Because of their extensive and long-term client relationships, Defendants were in a
4 unique position to know how the entire industry's opioid sales and marketing tactics were playing
5 out, both in terms of return on investment for their individual clients, as well as overall market
6 trends such as the rise of the opioid crisis. Endo may not have known the specifics of competitor
7 Purdue's marketing efforts for OxyContin, just as Purdue may not have known the specifics of
8 Janssen's Nucynta plan. But McKinsey, Publicis, and ZS knew all three, as well as what Teva and
9 others were doing with their own branded opioid sales and marketing efforts *in real time*.

10 971. As the modern opioid epidemic became apparent and the subject of nationwide
11 attention, Defendants toiled diligently behind the scenes of several opioid manufacturers in the
12 pursuit of one goal: maximizing volumes and profits from the sale of these addictive and deadly
13 Schedule II controlled substances.

14 972. And so, through the affirmative acts undertaken by the Defendants, history repeats
15 itself. This time, however, the devastation is on a scale previously unimaginable.

16 **V. TOLLING OF STATUTES OF LIMITATION**

17 973. Defendants are equitably estopped from relying upon a statute of limitations
18 defense. Alongside their clients, Defendants undertook active efforts to deceive Plaintiff and to
19 purposefully conceal its unlawful conduct and fraudulently assure the public, including Plaintiff,
20 that opioids were non-addictive, effective, and safe for the treatment of long-term chronic pain and
21 non-acute, non-cancer pain with the goal of increased sales, greater availability and access to
22 opioids, and maximizing profits.

23 974. Defendants and their clients were deliberate in taking steps to conceal their
24 conspiratorial behavior and active role in the deceptive marketing of opioids. This deceptive
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1 marketing—which included the above falsehoods that opioids were safer, less subject to abuse, and
2 less addictive than other pain medications—was a substantial factor in the oversupply of opioids
3 through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

4 975. Defendants deliberately advised their clients on marketing strategies and tactics to
5 bolster their opioid products as non-addictive, safe, and efficacious without reliable scientific
6 evidence to support same, and implemented the same. Defendants’ services were given
7 confidentially, and both Defendants and their clients concealed the content of those services from
8 the public. In doing so, Defendants concealed their role in shaping, editing, and providing the
9 content of the false and misleading materials addressing pain management and opioids that were
10 widely disseminated to regulators, prescribers, and the public at large, including Plaintiff.

11 976. Defendants also concealed from Plaintiff the existence of the Plaintiff’s claims by
12 hiding their and their client’s lack of cooperation with law enforcement. For example, in May 2007,
13 Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what
14 the company acknowledged was an attempt to mislead doctors about the risk of addiction and
15 entered into a Corporate Integrity Agreement explained above. Purdue was ordered to pay \$600
16 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was
17 misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science.
18 Additionally, Michael Friedman, the company’s president, pled guilty to a misbranding charge and
19 agreed to pay \$19 million in fines; Howard R. Udell, Purdue’s top lawyer, also pled guilty and
20 agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty
21 as well and agreed to pay \$7.5 million in fines.

22 977. Nevertheless, even after the guilty pleas, Purdue continued to pay doctors on
23 speakers’ bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund
24 seemingly neutral organizations to disseminate the message that opioids were non-addictive as well
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1 as other misrepresentations. Purdue also assembled an army of lobbyists to fight any legislative
2 actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller
3 producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying
4 and political contributions—eight times what the gun lobby spent during that period. Defendants
5 participated extensively in these actions and provided Purdue with strategies and assistance to
6 maximize sales as described in this Complaint. Defendants knew that the actions they took with
7 Purdue were unlawful, and yet deliberately proceeded in order to increase Purdue's sales and
8 profits, and in turn to serve Defendants' financial interests.

10 978. Defendants affirmatively sought to convince the public that its clients' legal duties
11 to report suspicious sales of opioids had been satisfied through public assurances that they were
12 working to curb the opioid epidemic. For example, after the 2007 Purdue guilty plea described
13 above, Defendants provided services to protect the company's public image and sales, aiding in the
14 concealment of the addictive nature and dangers associated with opioid use and denying blame for
15 the epidemic, attributing it instead solely to abuse and inappropriate prescribing. At the guidance
16 and advice of Defendants, Purdue and others publicly portrayed themselves as committed to
17 working diligently with law enforcement and others to prevent diversion of these dangerous drugs
18 and curb the opioid epidemic, and they made broad promises to change their ways, insisting they
19 were good corporate citizens. Instead, Defendants assisted Purdue, for example, with marketing
20 campaigns and messaging that continued business as usual, indiscriminately targeting high
21 prescribers and promoting opioids as safe but avoiding the pitfalls of the Corporate Integrity
22 Agreement. These repeated misrepresentations misled regulators, prescribers, and the public,
23 including the Plaintiff, and deprived Plaintiff of actual or implied knowledge of facts sufficient to
24 put the Plaintiff on notice of potential claims.

1 979. Plaintiff did not discover the nature, scope, and magnitude of Defendants'
2 misconduct, and its full impact on Plaintiff, and could not have acquired such knowledge earlier
3 through the exercise of reasonable diligence.

4 980. Prior to the applicable limitations period, Plaintiff did not suspect, and had no reason
5 to suspect, that Defendants' conduct caused their injuries, including the consumption of Plaintiff's
6 resources as the opioid epidemic remains unabated.

7 981. Defendants intended that its actions and omissions made with its clients would be
8 relied upon, including by the Plaintiff. The Plaintiff did not know and did not have the means to
9 know the truth due to Defendants' and their clients' actions and omissions.

10 982. The Plaintiff reasonably relied on the affirmative statements developed by
11 Defendants and made by their clients regarding their purported compliance with their obligations
12 under the law and consent orders, which were false and only intended to save the clients' public
13 image.

14 983. Defendants' fraudulent concealment has tolled the running of any statute of
15 limitations. Through their and their clients' affirmative misrepresentations and omissions,
16 Defendants actively concealed from Plaintiff the risks associated with opioids that led to the opioid
17 crisis. The wrongdoing, misrepresentations, and omissions by Defendants have not ceased because
18 the public nuisance remains unabated.

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26 **VI. CAUSES OF ACTION**

27 **COUNT I:**
28 **Racketeer Influenced and Corrupt Organizations Act (RICO)**

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2 984. Plaintiffs re-allege all of the foregoing allegations and incorporate them herein by
3 reference.

4 985. This claim is brought by Plaintiffs against Defendants for actual damages, treble
5 damages, and available injunctive and/or equitable relief under 18 U.S.C. § 1964, for violations of
6 18 U.S.C. § 1961, *et seq.*, specifically, 18 U.S.C. § 1962(c) and (d).

7 986. Section 1962(c) makes it “unlawful for any person employed by or associated with
8 any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to
9 conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a
10 pattern of racketeering activity” 18 U.S.C. § 1962(c).

11 987. At all relevant times, each Defendant is and has been a “person” under 18 U.S.C. §
12 1961(3) because each is capable of holding, and does hold, “a legal or beneficial interest in
13 property.”

14 988. Plaintiffs are each a “person,” as the term is defined in 18 U.S.C. § 1961(3), and
15 have standing to sue under 18 U.S.C. § 1964(c) as they were and are injured in their business and/or
16 property “by reason of” the RICO Act violations described herein.

17 989. Section 1962(d) makes it unlawful for “any person to conspire to violate” Section
18 1962(c), among other provisions. See 18 U.S.C. § 1962(d).

19 990. Defendants conducted the affairs of an enterprise through a pattern of racketeering
20 activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

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26 **Description of the Enterprise**
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1 991. Section 1961(4) defines an enterprise as “any individual, partnership, corporation,
2 association, or other legal entity, and any union or group of individuals associated in fact although
3 not a legal entity.” 18 U.S.C. § 1961(4).

4 992. Under 18 U.S.C. § 1961(4), a RICO “enterprise” may be an association-in-fact that,
5 although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those
6 associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise’s purpose. *See*
7 *Boyle v. United States*, 556 U.S. 938, 946 (2009).

9 993. Opioid manufacturers, including Purdue, Johnson & Johnson, Janssen, Cephalon,
10 Endo, and Mallinckrodt (collectively the “Opioid Manufacturers”), together with Defendants and
11 McKinsey (“the Opioid Consultants”), participated in the marketing and sale of opioids as
12 described in this Complaint, (collectively, the “Opioid Marketing Enterprise Members” or the
13 “Enterprise Members”) engaged in a scheme to unlawfully increase sales of opioids— both by
14 growing their share of the prescription painkiller market *and* by growing the market as a whole—
15 through repeated and systematic misrepresentations, concealments, and omissions of material fact
16 about the safety and efficacy of opioids for treating long-term chronic pain, together with other
17 deceptive and fraudulent acts and practices, as described in the Factual Allegations section of this
18 Complaint and in the Master Consolidated Complaint filed by Plaintiffs in MDL 2996 on December
19 6, 2021, *cf.* Dkt. 300 (Tribal Plaintiffs Master Complaint).

21 994. In order to unlawfully increase the demand for opioids and thereby increase their
22 own profits despite their knowledge of the harmful effects that would follow, the Opioid Marketing
23 Enterprise Members formed an association-in-fact enterprise (the “Opioid Marketing Enterprise”
24 or the “Enterprise”). The Opioids Manufacturers worked together to accomplish their aims, with
25 McKinsey and Defendants serving as go-betweens that held all of the companies together and
26 helped design and coordinate the deceptive marketing and sales strategies. Through McKinsey and
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1 Defendants and their own personal relationships, the members of the Opioid Marketing Enterprise
2 had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's
3 common purpose: lying to prescribers and Plaintiffs in order to increase sales of addictive and
4 dangerous drugs and line the enterprise members' pockets. The Opioid Marketing Enterprise
5 Members' substantial financial contributions to the Opioid Marketing Enterprise and the
6 advancement of opioids-friendly messaging fueled the U.S. opioid epidemic.
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8 995. In the alternative, the association-in-fact Opioid Marketing Enterprise existed just
9 between McKinsey, Defendants, and Purdue, who worked together to unlawfully increase sales of
10 *all* opioids—not just Purdue's own products—through repeated and systematic misrepresentations
11 about the safety and efficacy of opioids for treating long-term chronic pain. McKinsey and
12 Defendants knew Purdue was marketing its opioids illegally and fueling an opioid epidemic, but
13 using the knowledge gained from Defendants' and McKinsey's work with other opioid
14 manufacturers, Defendants and McKinsey joined forces with Purdue to turbocharge the opioids
15 market in order to profit from this crisis.
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17 996. The Controlled Substances Act (the "CSA") and its implementing regulations
18 require that "[e]very person who manufactures, distributes, dispenses, imports, or exports any
19 controlled substance," including opioids, become a "registrant." *See* 21 U.S.C. § 823(a)-(b); 21
20 C.F.R. § 1301.11(a). These registrants, including opioid manufacturer and distributors, must
21 maintain a system to identify and report suspicious orders, including orders of unusual size or
22 frequency, or orders deviating from a normal pattern, and maintain effective controls against
23 diversion of controlled substances. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).
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25 997. Despite these duties, Defendants, McKinsey and the other Enterprise Members
26 engaged in a scheme with the overarching purpose of materially expanding prescription opioid use
27 by altering the medical community's opioid prescribing practices through repeated fraudulent
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1 statements and misrepresentations. The Opioid Marketing Enterprise's scheme was sophisticated,
2 well-developed, and fraudulent and was designed to increase the prescription rate for opioid
3 medications the Enterprise Members knew were dangerous and highly addictive. At all relevant
4 times, Defendants and McKinsey were aware of the conduct of the Enterprise, were knowing and
5 willing participants in that conduct, and reaped profits from that conduct in the form of payments
6 from other Enterprise Members as a reward for work done to increase sales and distribution of
7 prescription opioids.

9 **The Common Purpose and Scheme of the Opioid Marketing Enterprise.**

10 998. The Opioid Marketing Enterprise Members, through the Opioid Marketing
11 Enterprise, concealed the true risks and dangers of opioids from the medical community and
12 Plaintiffs and made misleading statements and misrepresentations about opioids that downplayed
13 the risk of addiction and exaggerated the benefits of opioid use. These misleading statements
14 included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk
15 can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually
16 symptoms of an invented condition, which the Opioid Marketing Enterprise Members named
17 "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no
18 significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative
19 forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released
20 dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid
21 abuse.

24 999. The scheme devised, implemented, and conducted by the Opioid Marketing
25 Enterprise Members was a common course of conduct designed to ensure that the Opioid Marketing
26 Enterprise Members unlawfully increased their sales and profits through concealment and
27 misrepresentations about the addictive nature and effective use of the Opioid Manufacturers' drugs.
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1 The Opioid Marketing Enterprise Members acted together for a common purpose and perpetuated
2 the Opioid Marketing Enterprise's scheme.

3 1000. There was regular communication between the Opioid Marketing Enterprise
4 Members in which information was shared, misrepresentations were coordinated, and payments
5 were exchanged. The Opioid Marketing Enterprise Members functioned as a continuing unit for
6 the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and
7 each agreed and took actions to hide the scheme and continue its existence.
8

9 1001. As public scrutiny and media coverage focused on how opioids ravaged
10 communities throughout the United States, Defendants and McKinsey did not challenge Purdue or
11 other manufacturers' misrepresentations, seek to correct their previous misrepresentations,
12 terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using
13 opioids for chronic pain outweighed their benefits and were not supported by medically acceptable
14 evidence. Instead, despite its knowledge of the ongoing fraud and the danger it posed, Defendants
15 and McKinsey continued to participate in the Opioid Marketing Enterprise for financial gain.
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17 1002. The impact of the Opioid Marketing Enterprise's scheme is still in place—i.e., the
18 opioids continue to be prescribed and used for chronic pain throughout the United States, and the
19 epidemic continues to injure Plaintiffs and consume the resources of Plaintiffs.
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21 1003. The evidence shows that the Opioid Marketing Enterprise Members, including
22 Defendants and McKinsey, were each willing participants in the Opioid Marketing Enterprise, had
23 a common purpose and interest in the object of the scheme, and functioned within a structure
24 designed to effectuate the Enterprise's purpose.
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28 **The Conduct of the Opioid Marketing Enterprise Violated Civil RICO.**

1 1004. From at least 2004 to the present, each of the Opioid Marketing Enterprise Members
2 played some part in directing the affairs of the Opioid Marketing Enterprise and participated in the
3 operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly,
4 in the following ways:

5 1005. Creating and providing a body of deceptive, misleading, and unsupported medical
6 and popular literature about opioids that (i) understated the risks and overstated the benefits of long-
7 term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more
8 likely to be relied upon by physicians, patients, and payors;

9 1006. Creating and providing a body of deceptive, misleading, and unsupported electronic
10 and print advertisements about opioids that (i) understated the risks and overstated the benefits of
11 long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus
12 more likely to be relied upon by physicians, patients, and payors;

13 1007. Creating and providing a body of deceptive, misleading, and unsupported sales and
14 promotional training materials about opioids that (i) understated the risks and overstated the
15 benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii)
16 was thus more likely to be relied upon by physicians, patients, and payors;

17 1008. Devising and implementing marketing schemes that included targeting and
18 misleading physicians, unlawfully incentivizing sales representatives to maximize prescriptions
19 and dosages, and evading regulatory constraints; and

20 1009. Disseminating many of their false, misleading, imbalanced, and unsupported
21 statements through unbranded materials that appeared to be independent publications.

22 1010. The scheme devised and implemented by the Opioid Marketing Enterprise Members
23 amounted to a common course of conduct intended to enrich themselves by increasing sales of
24 prescription opioids by convincing doctors to prescribe and patients to use opioids, including for
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1 long-term chronic pain, despite the Opioid Marketing Enterprise Members' knowledge of the
2 addictions and deaths that would occur as a result. The scheme was a continuing course of conduct,
3 and many aspects of it continue through to the present.

4 **The Opioid Marketing Enterprise Members Conducted or Participated, Directly or**
5 **Indirectly, in the Conduct of the Enterprise's Affairs.**
6

7 1011. "[T]o conduct or participate, directly or indirectly, in the conduct" of an enterprise,
8 "one must participate in the operation or management of the enterprise itself." *Reves v. Ernst &*
9 *Young*, 507 U.S. 170, 185 (1993).

10 1012. As described herein, the Opioid Marketing Enterprise Members participated in the
11 conduct of the Enterprise through a pattern of racketeering activity, and Defendants and McKinsey
12 were the masterminds of marketing schemes deployed by the Enterprise members to defraud
13 prescribers and Plaintiffs by using the mail and wires in furtherance of plans that were designed
14 with specific intent to defraud.
15

16 1013. The Opioid Marketing Enterprise Members conducted an association-in-fact
17 enterprise and/or participated in the conduct of an enterprise through a pattern of illegal activities
18 (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the
19 Opioid Marketing Enterprise, i.e., to unlawfully increase profits and revenues from the continued
20 prescription and use of opioids for long-term, chronic pain. Through the racketeering activities of
21 the Opioid Marketing Enterprise, the Opioid Marketing Enterprise Members sought to further the
22 common purpose of the Enterprise through a fraudulent scheme to change prescriber habits and
23 public perception about the safety and efficacy of opioid use. In so doing, each of the Opioid
24 Marketing Enterprise Members knowingly conducted and participated in the conduct of the
25 Enterprise by engaging in mail and wire fraud, in violation of 18 U.S.C. §§ 1962(c) and (d).
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1 1014. The Opioid Marketing Enterprise is an association-in-fact enterprise that consists of
2 the Opioid Marketing Enterprise Members.

3 1015. Each of the Opioid Marketing Enterprise Members conducted and participated in
4 the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the
5 Enterprise's common purpose of increasing profits and sales through the knowing and intentional
6 dissemination of false and misleading information about the safety and efficacy of long-term opioid
7 use, and the risks and symptoms of addiction, in order to increase the market for prescription
8 opioids by changing prescriber habits and public perceptions.

9 1016. Specifically, the Opioid Marketing Enterprise Members each worked together to
10 coordinate the Enterprise's goals and conceal their role, and the Enterprise's existence, from
11 prescribers and Plaintiffs by, among other things, (i) funding, creating, editing, and distributing
12 publications that supported and advanced their false messages; (ii) funding key opinion leaders
13 ("KOLs") to further promote their false messages; and (iii) tasking their own employees to direct
14 deceptive marketing materials and pitches directly at physicians.

15 1017. Further, each of the Opioid Marketing Enterprise Members had systematic links to,
16 and personal relationships with, each other through joint participation in lobbying groups, trade
17 industry organizations, contractual relationships, and continuing coordination of activities. The
18 systematic links and personal relationships that were formed and developed allowed the Opioid
19 Marketing Enterprise Members the opportunity to form the common purpose and agree to conduct
20 and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the Opioid
21 Marketing Enterprise Members coordinated their efforts through the same KOLs and front groups,
22 based on their agreement and understanding that the front groups and KOLs were industry friendly
23 and would work together with the Opioid Marketing Enterprise Members to advance the common
24 purpose of the Opioid Marketing Enterprise; and each of the individuals and entities who formed
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1 the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the
2 Opioid Marketing Enterprise.

3 1018. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate
4 and distinct from each Opioid Manufacturer and its members; (b) was separate and distinct from
5 the pattern of racketeering in which the Opioid Marketing Enterprise Members engaged; (c) was
6 an ongoing and continuing organization consisting of individuals, persons, and legal entities,
7 including each of the Opioid Marketing Enterprise Members; (d) was characterized by interpersonal
8 relationships between and among each member of the Opioid Marketing Enterprise; and (e) had
9 sufficient longevity for the Enterprise to pursue its purpose and functioned as a continuing unit.
10

11 1019. The Opioid Marketing Enterprise Members conducted and participated in the
12 conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed
13 the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire
14 fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order
15 to increase the prescription and use of prescription opioids and expand the market for opioids.
16

17 1020. The Opioid Marketing Enterprise Members each committed, conspired to commit,
18 and/or aided and abetted in the commission of at least two predicate acts of racketeering activity
19 (i.e., violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of
20 racketeering activity that the Opioid Marketing Enterprise Members committed, or aided and
21 abetted in the commission of, were related to each other, posed a threat of continued racketeering
22 activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was
23 made possible by the Opioid Marketing Enterprise Members’ regular use of the facilities, services,
24 distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail, and
25 interstate wire facilities. The Opioid Marketing Enterprise Members participated in the scheme to
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defraud by using mail, telephones, and the internet to transmit communications and payments in interstate or foreign commerce.

The Conduct was More than a Typical Business Relationship.

1021. There were strong relationships among those associated with the Opioid Enterprise and sufficient longevity among Enterprise associates to pursue the Enterprise’s common purpose. The common purpose was to increase opioid revenues unlawfully by misrepresenting and lying about opioids in order to changing prescriber habits and the perception regarding the safety and efficacy of opioids for chronic pain and long-term use. The Enterprise’s deceit was, in part, in its failure to disclose that increasing strength and dosing actually increased the risk of addiction and overdose and that patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief.

1022. On March 1, 2004, McKinsey entered into a “Master Consulting Agreement” with Purdue for “services that would be defined from time to time.”⁷¹⁴ The Master Consulting Agreement was signed by then-McKinsey director Rob Rosiello.”⁷¹⁵

1023. From 2004 through 2008, McKinsey advised Purdue on research and development, business development, and product licensing related to Purdue’s opioid products.⁷¹⁶ Consistent with its business model, McKinsey leveraged these projects into growth of its “Broader Strategy work” also underway with Purdue.⁷¹⁷ Specifically, in October 2008, Purdue retained McKinsey for broad strategy work after two board members “blessed” Purdue executive Craig Landau with doing “whatever he thinks is necessary to ‘save the business’” after the 2007 criminal plea and introduction of generic competition to the older OxyContin.⁷¹⁸ Purdue relied heavily on McKinsey

⁷¹⁴ MCK-MDL2996-0085849; PPLPC012000069192

⁷¹⁵ MCK-MDL2996-0085849, at 0085880.

⁷¹⁶ PPLPC013000116218; PPLP004401340

⁷¹⁷ MCK-MAAG-0117875

⁷¹⁸ MCK-MAAG-0117875

1 to help Purdue publicly portray itself as a good corporate citizen who could now be trusted and was
2 even working on an “abuse-deterrent” or “ADF” form of OxyContin. Defendant Publicis worked
3 intimately with McKinsey is designing and disseminating these messages to their intended
4 audience.

5
6 1024. Over their many years of working together, McKinsey and Richard Sackler
7 developed a close relationship. Indeed, one McKinsey partner, Maria Gordian, describes herself as
8 a counselor to Richard Sackler in an “Ey 2009 Impact Summary.”⁷¹⁹

9 1025. For Publicis’ part, they owned their client. Publicis’ Karl Tiedemann noted in an
10 email the “amazing relationship” developing between Purdue and Publicis, and quoted a Purdue
11 employee as stating that the Hysinglia account was “the final piece and **we now own Purdue.**”
12 (emphasis added).

13
14 1026. The Opioid Marketing Enterprise was more than a typical business relationship.
15 Rather, the members of the Enterprise knew that opioids were addictive and causing serious harm
16 to people and communities but chose to work together to lie to prescribers and Plaintiffs about these
17 drugs in order to increase their bottom lines. Defendants and McKinsey worked closely with the
18 Opioid Manufacturers to achieve these aims. Defendants and McKinsey, as advisors to multiple
19 Opioid Manufacturers, also had access to information about multiple players and was able to
20 coordinate the fraud occurring across the Enterprise. As discussed below, McKinsey was
21 particularly embedded in Purdue’s organizational structure and the relationship’s longevity was
22 sufficient to pursue the Enterprise’s purposes. During the 2009-2014 period in particular, Purdue
23 relied extensively on McKinsey to develop its sales and marketing strategy for OxyContin. Publicis
24 worked with McKinsey and Purdue to craft and disseminate these strategies by using targeting and
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⁷¹⁹ MCK-MAAG-0118669

1 salesforce optimization methods designed by ZS and distribution channels offered by Practice
2 Fusion.

3 1027. The intent to defraud is evident in the Defendants and McKinsey's attempts to
4 strengthen their relationships with Purdue and assist Purdue in selling opioids after Purdue's 2007
5 criminal guilty plea. As part of the guilty plea, Purdue admitted that its "supervisors and employees,
6 with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less
7 subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain
8 medication."⁷²⁰ But rather than be deterred by this, Defendants and McKinsey dove in. In a March
9 2009 self-assessment, Ms. Gordian described McKinsey's progress in having "continue[d] to
10 expand the depth and breadth of [its] relationships with Purdue" and plans to "deepen[]"
11 McKinsey's "relationship with the Sackler family," including by "serving them on key business
12 development issues" and "expanding" McKinsey's relationship with members of Purdue's senior
13 management team.⁷²¹ Meanwhile, internal Rosetta communications refer to Publicis "owning"
14 Purdue given the extent of their relationship with the client, to wit, "we now own them."

15 1028. By August 2009, Richard Sackler had convened a meeting of Purdue board members
16 and staff to discuss efforts to "reverse the decline in the OxyContin tablets market."⁷²² During the
17 2009-2014 period in particular, Purdue relied extensively on Defendants and McKinsey to develop
18 and implement sales and marketing strategy for OxyContin. Defendants and McKinsey worked
19 closely with Purdue on both the creation and implementation of OxyContin sales strategy.
20 McKinsey's work for Purdue included consulting, review of product acquisition, evaluation of
21 research and development, advising Purdue on the design of clinical studies, risk management, and
22 product marketing.⁷²³

23 ⁷²⁰ Information at pp. 5-6, *United States v. Purdue Frederick Co.*, No. 07-cr-29-JPJ (W.D. Va. May 10, 2007), Doc. 5.

24 ⁷²¹ MCK-MAAG-0118669

25 ⁷²² PPLPC061000045395

26 ⁷²³ PPLPC029000547371

1029. On May 28, 2013, McKinsey entered into a “Statement of Services to the Master Consulting Agreement” (the “2013 Agreement”) with Purdue to “conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities.”⁷²⁴ The 2013 Agreement stated, “We have a long history of partnership with Purdue, and we would make best efforts to leverage our understanding of your business—both in terms of content and culture.” The 2013 Agreement was signed by then-principal Arnab Ghatak who would “lead the team with senior leadership from Rob Rosiello and Martin Elling.”

1030. [REDACTED]

Throughout that time period, Defendants worked alongside Purdue and McKinsey to design, implement and disseminate these strategies.

1031. Thereby, even after the 2007 guilty plea, Purdue, with Defendants and McKinsey’s ongoing aid and assistance, saw growing profits from opioid sales. In 2015 alone, Purdue obtained \$3 billion in annual opioid sales—a four-fold increase from its 2006 sales of \$800 million.

1032. Defendants and McKinsey’s relationship with Purdue went far beyond a typical business relationship. Defendants and McKinsey worked closely with Purdue on both the creation and implementation of OxyContin sales strategy, a strategy Defendants and McKinsey knew had been based on misleading and defrauding doctors and patients alike about a dangerous and highly addictive drug. McKinsey and Defendants interacted with Purdue at all levels of the corporate

⁷²⁴ Excerpt from U.S. Department of Justice Plea Agreement with Purdue Pharma L.P. October 20, 2020. 18, ¶88. <https://www.justice.gov/opa/press-release/file/1329576/download>.

⁷²⁵ PPLPC018001462324 [REDACTED]

1 hierarchy – from fields sales representative all the way up to Purdue’s Sackler-controlled board of
2 directors.

3 1033. Further, Defendants and McKinsey had access to detailed prescribing information
4 enabling them to determine if there were suspicious or problematic prescribing patterns. Rather
5 than using this information to help their clients prevent diversion of controlled substances,
6 Defendants and McKinsey and the Opioid Marketing Enterprise used this information in
7 furtherance of their scheme to defraud prescribers and Plaintiffs, target and increase sales to
8 prescribers who were overprescribing, and continue to fuel opioid addiction and the resulting
9 epidemic.
10

11 **The Fraudulent Schemes**

12 1034. As detailed above, the operation of the Opioid Marketing Enterprise, included
13 several schemes to defraud that helped to further the goals its members—i.e., to expand the market
14 and increase profits and sales through the knowing and intentional dissemination of false and
15 misleading information about the safety and efficacy of long-term opioid use, and to increase profits
16 for the Enterprise Members via expanding the market for opioids.
17

18 **Fraudulent Marketing Scheme: Deceptive Messaging Regarding Opioid Use**

19 1035. As described throughout, Defendants and McKinsey sought to unlawfully increase
20 profits and revenues from the continued prescription and use of opioids for long-term, chronic pain
21 by changing prescriber habits and public perception regarding the safety and efficacy of opioids.
22 Defendants’ and McKinsey’s fraud specifically targeted prescribers and set out to convince them
23 that they should prescribe more and more opioids, overcoming what could otherwise be a check on
24 opioid manufacturers ability to increase sales of addictive products.
25

26 1036. Despite Defendants and McKinsey knowing that reformulated OxyContin could still
27 be abused, having advised Purdue on the design of tests of reformulated OxyContin as part of
28

1 Purdue's FDA submission,⁷²⁶ in furtherance of the scheme to defraud, Defendants and McKinsey
 2 spread messages that prescribing opioids could provide "freedom" and "peace of mind" for its users
 3 and that physicians could "tailor the dose."

4 1037. After Purdue's 2007 criminal plea for illegally marketing OxyContin, Defendants
 5 and McKinsey created strategies to repair Purdue's reputation and boost OxyContin sales. In 2008,
 6 Purdue submitted a New Drug Application for a reformulation of OxyContin, ostensibly to make it
 7 more difficult to abuse by extracting the active ingredient from it or otherwise defeating the time-
 8 release mechanism in OxyContin tablets—i.e., another product Purdue would later deceptively
 9 promote as safer than and less prone to abuse than it was.

10 1038. In June 2009, McKinsey helped Purdue prepare for an FDA advisory committee
 11 meeting. [REDACTED]
 12 [REDACTED]
 13 [REDACTED]
 14 [REDACTED]
 15 [REDACTED]
 16 [REDACTED]

17 1039. McKinsey prepared for Purdue an "FDA Advisory Committee on Reformulated
 18 OxyContin: Question & Answer Book" in September 2009, with questions including "Why should
 19 we trust you?" In response, McKinsey recommended Purdue say "We acknowledge mistakes made
 20 in the past[;]" "We have x, y and z measures in place that did not exist before[;]" and "[a]t all levels,
 21 Purdue's focus is on maintaining the highest ethical standards and meeting the needs of
 22 patients[.]"⁷²⁹ To the question of "Who at Purdue takes personal responsibility for all these
 23 deaths?[,]" McKinsey recommended Purdue say, "We all feel responsible[.]"
 24
 25
 26

27 ⁷²⁶ McK-MAAG-0118669

28 ⁷²⁷ PDD8901645845

⁷²⁸ *Id.*

⁷²⁹ MCK-MAAK-0152135

1 1040. As described above, Defendant Publicis also engaged in work with the FDA, and
2 through that work was able to disseminate messages consistent with Purdue's strategy to increase
3 overall opioid prescribing.

4 1041. Defendants and McKinsey and the other Opioid Marketing Enterprise Members
5 knew the changes Purdue made would not make opioids non-addictive or prevent them from being
6 used to create and further substance abuse problems. For example, in 2009, the FDA noted in
7 permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the
8 oral route (the most common mode of abuse)." Similarly, in approving reformulated OxyContin,
9 the FDA cautioned that the reformulation "is not completely tamper resistant and those intent on
10 abusing this new formulation will likely find a means to do so. In addition, the product can still be
11 misused or abused and result in overdose by simply administering or ingesting larger than
12 recommended oral doses."⁷³⁰

13
14
15 1042. Despite this knowledge, the Opioid Marketing Enterprise pursued messaging and a
16 strategy that was deceptive and was designed to deceive doctors in particular. Even after Purdue
17 pleaded guilty to offenses related to its marketing and distribution of addictive opioids, Defendants
18 and McKinsey advised Purdue to market OxyContin to encourage more prescriptions (that it knew
19 would lead to abuse and overdose events) into higher dose prescriptions by a smaller number of
20 loyalist prescribers.

21
22 1043. Rather than the deception of doctors being an unforeseen consequence, Defendants
23 and McKinsey intentionally set out to target doctors as a cog in the Enterprise's scheme to defraud.
24 Indeed, deceiving doctors was part of the marketing scheme, and doctors were utilized in
25 furtherance of the marketing scheme. Medical providers were not a break in the causal chain of
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⁷³⁰ FDA Summary Review, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000SumR.pdf

1 harm to Plaintiffs but were targeted players in the scheme to defraud and key links in the casual
2 chain.

3 1044. The marketing scheme involved using data to target high prescribers and training
4 marketers to make misleading statements with the goal to increase high dose prescriptions which
5 Defendants and McKinsey and Opioid Marketing Enterprise Members knew were more likely to
6 be abused. Enterprise Members knew that overdoses were expected and that such overdoses would
7 lead to need for increased services.
8

9 1045. Purdue's 2020 guilty plea acknowledged its role in using aggressive marketing to
10 convince doctors to prescribe opioids unnecessarily, fueling the drug addiction crisis. Defendants
11 and McKinsey were the masterminds of marketing scheme following Purdue's 2007 guilty plea.
12 Defendants and McKinsey developed and helped implement these strategies.
13

14 1046. In an October 26, 2009 presentation, "OxyContin – driving growth through stronger
15 brand loyalty," McKinsey proposed tactics to turnaround declining sales, "[e]nhance loyalty to
16 OxyContin among loyalist prescribers," "convert[ing] 'fence sitters' into more loyal OxyContin
17 prescribers,"⁷³¹ and "protect OxyContin's market share[.]"⁷³² In other words, McKinsey proposed
18 increasing sales by pushing both willing and reluctant physicians to prescribe more OxyContin.
19 Defendants worked assiduously alongside McKinsey to accomplish these goals.
20

21 1047. Defendants and McKinsey recommended segmenting prescribers and tailoring
22 messages and tactics to different segments. For prescribers dubbed "Early Adopting Experts" and
23 "Proactive Teachers," defined by a willingness to use extended release opioids, including in
24 patients who were not already using opioids, McKinsey urged emphasizing that its 7 tablet strengths
25 provide flexibility to "tailor the dose" to customer needs.⁷³³ Upon information and belief, this
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27 ⁷³¹ MCK-MDL2996-0126522

28 ⁷³² *Id.* at 2

⁷³³ *Id.* at 12.

1 message aimed to encourage prescribers to initiate and maintain patients on OxyContin long-term
 2 by reminding them they could increase the dose as patients became tolerant with long-term use
 3 (rather than discontinue use when the drug lost its effectiveness).

4 1048. Purdue adopted McKinsey's [REDACTED] proposal [REDACTED]
 5 [REDACTED]
 6 [REDACTED]
 7 [REDACTED]

8 [REDACTED] Defendants Publicis and ZS were integral to these [REDACTED] efforts, and
 9 Publicis worked for years to continually refine titration messaging for Purdue to ensure each
 10 prescription was as profitable as possible.

11 1049. As detailed throughout, Defendants and McKinsey and Opioid Marketing Enterprise
 12 Members were aware of the catastrophic injury inflicted on the public by selling harmful, addictive
 13 opioid products. Yet when promoting opioids and engaging in doctor detailing, the Enterprise
 14 Members intentionally hid the potential for abuse and addiction by marketing OxyContin's 12-hour
 15 dosing as meaning that users only need to take OxyContin twice a day, thus requiring fewer pills.
 16

17 1050. It was foreseeable that this marketing strategy would lead to greater addiction
 18 because OxyContin wore off after 8 to 10 hours in many patients. Prescribing 12-hour dosing led
 19 to "end of dose failure," which led to a vicious cycle that became "the perfect recipe for
 20 addiction."⁷³⁶ As a result, what Defendants and McKinsey marketed as "convenient" led to what
 21 was described as "a [d]escription of Hell."⁷³⁷
 22
 23
 24

25 ⁷³⁴ PPLPC023000251226 ([REDACTED]) see also
 26 PPLPC012000243668 ([REDACTED]) PPLPC012000245087 ([REDACTED])
 27 [REDACTED] PPLPC012000246009 ([REDACTED]) PPLPC021000265092 ([REDACTED])
 28 [REDACTED]

⁷³⁵ PKY183123435

⁷³⁶ Harriet Ryan, "'You Want a Description of Hell?' OxyContin's 12-Hour Problem," Los Angeles Times, May 5, 2016, available at <http://www.latimes.com/projects/oxycontin-part1/>.

⁷³⁷ *Id.*

1051. The marketing scheme worked. Nationwide, based on an analysis by the Los Angeles Times, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 morphine equivalent dose that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”⁷³⁸

1052. A key element of the marketing scheme that fueled the deadly epidemic of opioid abuse was doctor detailing using detailed prescriber data.

**Data Scheme: Use of Prescriber Data for Intentional Targeting of High Opioid Prescribers-
Not Diversion Prevention**

1053. Defendants and McKinsey were advisors to DEA registrants and Opioid Marketing Enterprise Members, who had a legal duty to guard against diversion and report suspicious orders of controlled substances. Rather than assisting in reporting suspicious orders, Defendants and McKinsey used their position and access to detailed prescriber information to actually divert resources to target high volume prescribers to sell more opioids.

1054. Distributors of controlled substances have a legal duty to report suspicious orders, and to report those that deviate substantially from a normal pattern and orders of unusual size and frequency. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b). These obligations included a legal duty to maintain effective controls and procedures to guard against diversion of controlled substances and a legal duty to maintain a system to identify and report suspicious orders of controlled substances. *See* 21 C.F.R. §§ 1301.7(a) (b); 1301.74(b). Rather than advising their registrant clients on how to comply with their legal duties to maintain effective controls to guard against diversion and how to operate a system to identify and report suspicious orders, in furtherance of the scheme, Defendants and McKinsey and the Opioid Marketing Enterprise Members used detailed data to target prescribers to increase the opioid market.

⁷³⁸ CDC Guideline at 16.

1 1055. Consistent with the Enterprise’s purpose of increasing profit by deceptively
2 marketing opioids, McKinsey was tasked with “Identifying Granular Growth Opportunities for
3 OxyContin,” conducting an “assessment of the underlying drivers of current OxyContin
4 performance,” identifying “key opportunities to drive near-term OxyContin performance,” and
5 developing “plans to capture priority opportunities.”⁷³⁹ Defendants assisted and collaborated with
6 McKinsey to identify and exploit these growth opportunities and drivers of near-term performance,
7 and implemented plans to capture these opportunities.

9 1056. Defendants and McKinsey received physician-level sales data to develop its
10 marketing strategy to increase OxyContin performance after Purdue’s 2007 guilty plea. Rather than
11 using this access to the granular data to avoid diversion and to prevent Enterprise members from
12 targeting prescribers with suspicious prescribing patterns, Defendants and McKinsey used this
13 information to help the Opioid Marketing Enterprise members push more opioids on high volume
14 prescribers in furtherance of its schemes to defraud. The targets were chosen based on their history
15 of prescribing high doses of opioids in large quantities.

17 1057. One of the services the Enterprise used in furtherance of this scheme concerned the
18 use of data to help Purdue meet its goals. Defendants and McKinsey’s analysis for “Evolve to
19 Excellence” shows that Defendants and McKinsey had detailed information from which it could
20 discern, as could Purdue, whether a prescriber had problematic patterns suggesting operation as a
21 “pill mill,” including a shift to other opioids after OxyContin’s reformulation. Yet, Defendants and
22 McKinsey urged Purdue to target, and seek to increase the prescribing of, all of these prescribers
23 from whom it perceived Purdue could obtain greater profits.

25 1058. McKinsey found that Purdue did not “focus on the highest potential docs,” measured
26 both by the number of prescriptions and reimbursement considerations.⁷⁴⁰ A McKinsey analyst
27

28 ⁷³⁹ PPLPC030000770531

⁷⁴⁰ MCK-MDL2996-0364024

1 urged McKinsey to recommend Purdue target “[l]iterally, at least all” prescribers in the top 20% of
2 prescribers, “minus another few percent who are no sees[.]” McKinsey team lead Arnab Ghatak
3 replied that “they probably have 20% no see[], but i’d also assume there are not many high writers
4 that are no see.”⁷⁴¹ (“No see” prescribers are prescribers who do not accept visits from
5 pharmaceutical sales representatives. Thus, upon information and belief, McKinsey recognized that
6 most of the highest volume prescribers, or “high writers” of prescriptions, were willing to entertain
7 sales visits from sales representatives.) Defendant ZS assisted McKinsey with targeting these
8 prescribers, and Publicis assisted McKinsey with crafting messages to deliver to them.

10 1059. The Opioid Marketing Enterprise used data for intentional targeting of high
11 prescribers and not for diversion prevention. Defendants and McKinsey advised Purdue to raise
12 sales of Oxycontin by focusing on high dose sales and deceptively messaging to physicians that
13 OxyContin would improve function and quality of life. Defendants and McKinsey urged Purdue to
14 maximize sales by dictating which prescribers its sales representatives would target. For example,
15 McKinsey advised Purdue that it should take “specific actions” to increase sales of OxyContin,
16 including “Prescriber Targeting” and “Turbocharg[ing] Purdue’s Sales Engine.” Defendant ZS’s
17 work was particularly relevant to these efforts.

19 1060. Defendants and McKinsey targeted not just doctors but also nurse practitioners and
20 physician assistants, with McKinsey recommending Purdue “[d]ouble down on nurse practitioners
21 and physician assistants . . . as they represent a growing market segmentation of prescribers.”⁷⁴²

23 1061. The Enterprise’s scheme also explored ways to increase the amount of time sales
24 representatives spent in the field increasing opioid sales, and prioritizing OxyContin in incentive
25 compensation targets.⁷⁴³ Again, ZS’s work was particularly relevant to these efforts.

27 ⁷⁴¹ MCK-MDL2996-0364267

28 ⁷⁴² MCK-MDL2996-0303399

⁷⁴³ PPLPC012000437346

1 1062. By April 24, 2014, the plan was working and McKinsey reported that Purdue's
2 "sales force is selecting an increasing percentage of high-value OxyContin prescribers as
3 targets."⁷⁴⁴

4 1063. McKinsey ensured Purdue would benefit from the lessons learned by other
5 Enterprise members, stating that "its experience with other pharmaceutical companies suggests that
6 such a comprehensive Sales transformation program takes nine months."⁷⁴⁵ Likewise, McKinsey
7 recommended physician targeting to other Enterprise members, including Endo and Janssen.⁷⁴⁶
8 Similarly, ZS and Publicis were also advising multiple Opioid Marketing Enterprise members at
9 the same time.
10

11 1064. By targeting physicians based on their prescribing patterns, the Opioid Marketing
12 Enterprise was working toward the common purpose of deceptively convincing doctors to prescribe
13 more opioids and thereby increase their own profits. By developing "Evolve to Excellence," which
14 was implemented as a plan to "turbocharge" opioid sales, McKinsey advised that Purdue would see
15 a greater return on its sales investment by focusing its targets, including on prescribers with
16 alarming prescribing patterns that raised red flags they were writing "prescriptions" for non-
17 medical use. Defendants worked for years with McKinsey to accomplish these goals. The plan
18 aimed at boosting sales of OxyContin by targeting the highest volume opioid prescribers, which
19 Defendants and McKinsey and the other members of the Opioid Marketing Enterprise knew and/or
20 should have known would result in the expansion of the illicit opioid market.
21
22

23 1065. The Enterprise sought to grow opioid sales to prescribers who raised red flags of
24 diversion and orders it knew or should have known were likely to be diverted or fuel an illegal
25 market. Purdue had a legal obligation not to target these prescribers; rather, it was obligated to
26

27 _____
⁷⁴⁴ MCK-MDL2996-0104840; PPLPC035000220406

28 ⁷⁴⁵ MCK-MDL2996-0187168

⁷⁴⁶ MCK-MDL2996-0130803; MCK-MDL2996-0135713

1 report their conduct to law enforcement. Yet the Enterprise used access to prescriber data not to
2 report diversion but to enhance diversion.

3 **Pattern of Racketeering Activity**

4 1066. Defendants and McKinsey together with the other Opioid Marketing Enterprise
5 Members engaged in a scheme to unlawfully increase sales of opioids—and grow their share of the
6 prescription painkiller market—through repeated and systematic misrepresentations about the
7 safety and efficacy of opioids for treating long-term chronic pain. As a unique consulting entity
8 with knowledge of both the addictive properties and abuse potential of opioids and with access to
9 data regarding internal prescribing behaviors of its targets, McKinsey perpetrated – with
10 Defendants ongoing aid and assistance – a number of fraudulent schemes using the mails and wires,
11 including advising Purdue to market more opioids, in higher doses, to high volume prescribers
12 while helping Purdue avoid mandatory prescriber education regarding the risks of opioids.
13 Defendants and McKinsey fueled the epidemic alongside their clients. Through targeted marketing
14 that Defendants and McKinsey developed, “turbocharged,” and implemented, Defendants and
15 McKinsey substantially contributed to an explosion in the use of opioids across the United States.
16 Defendants and McKinsey are engaged in and affect interstate commerce because they advised
17 multiple opioid manufacturers headquartered on different states on the sale of opioid products
18 across the United States, as alleged herein.

19 1067. The Opioid Marketing Enterprise Members devised and knowingly carried out this
20 illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses,
21 representations, promises, or omissions of material facts regarding the safe, non-addictive and
22 effective use of opioids for long-term chronic, non-acute, and non-cancer pain. They knew that
23 these representations deviated from the FDA-approved use of these drugs and were not supported
24 by actual evidence. The Opioid Marketing Enterprise Members intended that their common purpose
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1 and scheme to defraud would, and did, deceive consumers, prescribers, regulators, Plaintiffs, and
2 other intended victims and they used the U.S. Mail and interstate wire facilities with the specific
3 intent to advance, and for the purpose of executing, their illegal scheme.

4 1068. By intentionally concealing the material risks and affirmatively misrepresenting the
5 benefits of using opioids for chronic pain, the Opioid Marketing Enterprise Members engaged in a
6 fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

7 1069. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the
8 Opioid Marketing Enterprise Members hid from the consumers, prescribers, regulators, and
9 Plaintiffs: (a) the fraudulent nature of the Opioid Marketing Enterprise Members' marketing
10 scheme; (b) the fraudulent nature of statements made by the Opioid Marketing Enterprise Members
11 regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship
12 between the members of the Opioid Marketing Enterprise.

13 1070. The Opioid Marketing Enterprise Members with knowledge and intent, to the
14 overall objective of the Opioid Marketing Enterprise Members' fraudulent scheme and participated
15 in the common course of conduct to commit acts of fraud and indecency in marketing prescription
16 opioids.

17 1071. Indeed, for the Opioid Marketing Enterprise Members' fraudulent scheme to work,
18 each of them had to agree to implement similar tactics regarding fraudulent marketing of
19 prescription opioids. This coordination was accomplished via their relationships with each other
20 and via Defendants and McKinsey's relationships and contacts with key opioids manufacturers.

21 1072. The Opioid Marketing Enterprise Members' predicate acts all had the purpose of
22 creating the opioid epidemic that substantially injured Plaintiffs, while simultaneously generating
23 billion-dollar revenues and profits for the Opioid Marketing Enterprise Members. The predicate
24 acts were committed or caused to be committed by the Opioid Marketing Enterprise Members
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1 through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent
2 scheme.

3 1073. The Opioid Marketing Enterprise Members' scheme described herein was
4 perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of
5 racketeering activity. Defendants and McKinsey used mail and wire transmission, directly or
6 indirectly, in furtherance of this scheme by transmitting deliberately false and misleading
7 statements to prescribers and the public.
8

9 1074. Defendants and McKinsey had a specific intent to deceive and defraud prescribers,
10 regulators and Plaintiffs. For example, as alleged above, Defendants and McKinsey made repeated
11 and unequivocal statements through the mails and wires that were false and misleading. For
12 example, McKinsey advised Purdue to market OxyContin based on the false and misleading notion
13 that the drug can provide "freedom" and "peace of mind" for its users, and concomitantly reduce
14 stress and isolation.
15

16 1075. Similarly, they caused to be transmitted through the mails and wires false and
17 misleading statements regarding the addiction potential of opioids. Moreover, Defendants and
18 McKinsey had direct involvement in marketing statements and thus caused the statements to be
19 made, notwithstanding that they knew they were false for the reasons detailed above.
20

21 1076. The marketing scheme is especially egregious since the public relies on physicians
22 as a position of trust and authority in the community regarding their health and well-being.
23 Defendants and McKinsey intentionally deceived physicians regarding the abuse potential of
24 opioids. It intended prescribers and the public to rely on its false statements. Defendants and
25 McKinsey intended reliance on these false statements as it was their goal for doctors to prescribe
26 more and higher quantities of these dangerous pills to the public. This scheme was therefore
27
28

1 reasonably calculated to deceive not only persons of ordinary prudence and comprehension but also
2 educated physicians in a place of high trust in the community.

3 **Predicate Acts**

4 1077. To carry out, or attempt to carry out, the scheme, the Enterprise Members, each of
5 whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate in,
6 directly or indirectly, the affairs of the Enterprise through a pattern of racketeering activity within
7 the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and
8 wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).
9

10 1078. Specifically, the Enterprise Members have committed, conspired to commit, and/or
11 aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e.,
12 violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

13 1079. The multiple acts of racketeering activity which the Enterprises Members
14 committed, or aided or abetted in the commission of, were related to each other, posed a threat of
15 continued racketeering activity, and therefore constitute a “pattern of racketeering activity.”
16

17 1080. The racketeering activity was made possible by the Enterprise’s regular use of the
18 facilities, services, distribution channels, and employees of the Enterprise Members.

19 1081. The Opioid Marketing Enterprise Members participated in the schemes by using
20 mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.
21

22 1082. The Enterprise Members used, directed the use of, and/or caused to be used,
23 thousands of interstate mail and wire communications in service of their schemes through common
24 misrepresentations, concealments, and material omissions.

25 1083. In devising and executing the illegal schemes, the Opioid Marketing Enterprises
26 Members devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs
27
28

1 and prescribers and to obtain money by means of materially false or fraudulent pretenses,
2 representations, promises, or omissions of material facts.

3 1084. For the purpose of executing the illegal schemes, the Enterprise Members
4 committed these racketeering acts, which number in the thousands, intentionally and knowingly
5 with the specific intent to advance the illegal schemes.
6

7 1085. The Opioid Marketing Enterprise Members' predicate acts of racketeering (18
8 U.S.C. § 1961(1)) include, but are not limited to the conduct described in the Factual Allegations
9 section of this Complaint, and:

10 1086. Mail Fraud: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1341
11 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or
12 commercial interstate carriers for the purpose of executing the unlawful scheme to design,
13 manufacture, market, and sell the prescription opioids by means of false pretenses,
14 misrepresentations, promises, and omissions.
15

16 1087. Wire Fraud: The Opioid Marketing Enterprise Members violated 18 U.S.C. § 1343
17 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire
18 for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the
19 prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
20

21 1088. The Opioid Marketing Enterprise Members' use of the U.S. Mail and interstate wire
22 facilities to perpetrate the opioids marketing scheme involved thousands separate instances of the
23 use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing
24 Enterprise, including essentially uniform misrepresentations, concealments, and material omissions
25 regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic,
26 non-acute, and non-cancer pain, with the goal of profiting from the increased sales of the Opioid
27 Marketing Enterprise Members' drugs that occurred because consumers, prescribers, regulators,
28

1 and Plaintiffs relied on the Opioid Marketing Enterprise Members' misrepresentations. These uses
2 of the U.S. Mail or interstate wires included, inter alia:

3 1089. Marketing materials about opioids and their risks and benefits, which the Opioid
4 Marketing Enterprise Members sent to health care providers, transmitted through the internet and
5 television, and published across the country, including in counties and cities and to Plaintiffs;
6

7 1090. Written representations and telephone calls among the Opioid Marketing Enterprise
8 Members and between the Opioid Marketing Enterprise Members regarding the misrepresentations,
9 marketing statements, and claims about opioids, including the non-addictive, safe use of opioids
10 for chronic, long-term pain generally;

11 1091. E-mails, telephone calls, and written communications among the Opioid Marketing
12 Enterprise Members agreeing to or implementing the opioids marketing scheme;
13

14 1092. Communications among the Opioid Marketing Enterprise Members and between
15 the Opioid Marketing Enterprise Members and the media regarding the publication, drafting, and
16 dissemination of treatment guidelines as part of the Opioid Marketing Enterprise;

17 1093. Written and oral communications directed to prescribers, the public, and Plaintiffs
18 that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
19

20 1094. Receipts of increased profits sent through the U.S. Mail and interstate wire
21 facilities—the wrongful proceeds of the scheme.

22 1095. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire
23 facilities are not obtainable (e.g., each time a McKinsey trained marketer "calls" or reached out to
24 a physician targeted by ZS with materials designed and prepared by Publicis using the mails or
25 wires in furtherance of the marketing scheme). Because the Opioid Marketing Enterprise Members
26 disguised their participation in the Enterprise, and worked to keep the Enterprise's existence secret,
27 many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate
28

wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the Opioid Marketing Enterprise Members. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. Plaintiffs have, however, described the types of predicate acts of mail and/or wire fraud, including the specific types of fraudulent statements upon which, through the mail and wires, Defendants and McKinsey engaged in fraudulent activity in furtherance of their scheme.

1096. The factual allegations in this Complaint describes multiple occasions of Defendants working to create and deliver to targeted audiences, including no-see prescribers, misrepresentations and false statements in furtherance of the scheme. Below, Plaintiffs also describe examples of occasions on which other Opioid Marketing Enterprise Members disseminated misrepresentations and false statements to consumers, prescribers, regulators, and Plaintiffs, and how those acts were also in furtherance of the scheme.

From	To	Date	Description
Purdue	Prescribers and Plaintiffs	2007	Statements that pain relief from opioids improves patients' function and quality of life in advertising and a book
Purdue	Prescribers	Continuous	Telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function
Purdue	FDA advisory committee	September 2009	Presentation prepared by McKinsey indicating that its reformulated OxyContin will deter abuse
Purdue	Prescribers and Plaintiffs	2010 onwards	Statements that the reformulated OxyContin will deter abuse and therefore doctors can continue to safely prescribe opioids
Purdue	Prescribers and Plaintiffs	2010-2020	Statements from Purdue at McKinsey's direction that opioids can provide "freedom," "peace of mind," and give patients "the best possible chance to live a full and active life"
Purdue	Prescribers and Plaintiffs	Advertising produced in 2016	Advertising from Purdue that "We sell hope in a bottle."
Purdue	Prescribers and Plaintiffs	2010 onwards	Statements that OxyContin's 12-hour dosing would allow patients to only need to take OxyContin twice a day, thus requiring fewer pills

1	Purdue	Prescribers and Plaintiffs	2013 onwards	Statements from Purdue at McKinsey's direction that OxyContin allowed physicians to "Individualize the Dose" and that the dose of OxyContin can safely be increased or tailored as the patients adapt to a certain dose
2				
3	Endo	Prescribers and Plaintiffs	2009	Statements made on an Endo-sponsored website, PainKnowledge.com, indicating that patients who take opioids as prescribed usually do not become addicted
4				
5	Endo	Prescribers and Plaintiffs	2009	Statements made on another Endo-sponsored website, PainAction.com, indicating that most chronic pain patients do not become addicted to opioid medications
6				
7	Endo	Prescribers and Plaintiffs	Various	Statements in pamphlets and publications described by Endo indicating that most people who take opioids for pain relief do not develop an addiction
8				
9	Endo	Prescribers and Plaintiffs	Various	Statements made on the Endo-run website, Opana.com, indicating that opioid use does not result in addiction
10				
11	Endo	Prescribers and Plaintiffs	Various	Statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosing methods such as tapering
12				
13	Endo	Prescribers and Plaintiffs	Various	Statements made on its website, PainKnowledge.com, that opioid dosages could be increased indefinitely
14				
15	Endo	Prescribers and Plaintiffs	Various	Statements made in a publication entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" suggesting that opioid doses can be increased indefinitely
16				
17	Endo	Prescribers and Plaintiffs	Various	Electronic and telephonic communications to its sales representatives indicating that the formula for its medicines is "crush resistant"
18				
19	Endo	Prescribers and Plaintiffs	2007	Statements that pain relief from opioids improves patients' function and quality of life in advertising and a book
20				
21	Endo	Prescribers and Plaintiffs	Various	Telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function
22				
23	Janssen	Prescribers and Plaintiffs	Various	Statements on its website, PrescribeResponsibly.com, indicating that concerns about opioid addiction are overestimated
24				
25	Janssen	Prescribers and Plaintiffs	2009	Statements in a 2009 patient education guide claiming that opioids are rarely addictive when used properly
26				
27	Janssen	Prescribers and Plaintiffs	2009	Statements included on a 2009 Janssen-sponsored website promoting the concept of opioid pseudoaddiction
28				
	Janssen	Prescribers and Plaintiffs	Various	Statements on its website, PrescribeResponsibly.com, advocating the concept of opioid pseudoaddiction
	Janssen	Prescribers and Plaintiffs	Various	Statements on its website, PrescribeResponsibly.com, indicating that opioid addiction can be managed
	Janssen	Prescribers and Plaintiffs	2009	Statements in its patient education guide indicating the risks associated with limiting the dosages of pain medicines

1	McKinsey	Purdue (with prescribers as the planned target)	July 18, 2013	Discussion of McKinsey plan to increase calls to doctors' offices to fraudulently promote OxyContin, including via "phone, video and even Google like proprietary tools" ⁷⁴⁷
2	McKinsey	Purdue (with prescribers as the planned target)	April 24, 2017	Plan to promote OxyContin to "no-see" physicians through "remote interactions" including presenting "brand interaction and materials" "over the phone/internet" ⁷⁴⁸
3	McKinsey	McKinsey	July 14, 2013	Internal emails interpreting "the Purdue situation" and discussing OxyContin sales strategy including sales benchmarks and "focus on the highest potential docs" ⁷⁴⁹
4	McKinsey	Purdue (with prescribers as the planned target)	September 23, 2013	Evolve 2 Excellence PowerPoint planning execution of the scheme and discussing targeted performance metrics including "sales management calls per day, calls per year and adhering to target list" ⁷⁵⁰
5	McKinsey	Purdue	July 30, 2013	Presentation showing "Scope of potential OxyContin growth opportunities" with proposed process including "Generate target list" and using "Reps/DMs [to] perform call planning (including refining target list)" ⁷⁵¹

1097. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the Opioid Marketing Enterprise Members defrauded and intended to defraud consumers, prescribers, regulators, Plaintiffs, and other intended victims.

1098. These were not isolated incidents. Instead, the Opioid Marketing Enterprise Members engaged in a pattern of racketeering activity by committing thousands of predicate acts in a five-year period, in the form of mail and wire fraud, and there remains a threat that such conduct will continue in the future.

⁷⁴⁷ MCK-MDL2996-0104431, at 0104442

⁷⁴⁸ MCK-MDL2996-0104840

⁷⁴⁹ MCK-MDL2996-0364024

⁷⁵⁰ MCK-MDL2996-0316833, at 0316834

⁷⁵¹ MCK-MDL2996-0303399

1 1099. Each instance of racketeering activity alleged herein was related, had similar
2 purposes, involved the same or similar participants and methods of commission, and had similar
3 results affecting similar victims, including consumers, prescribers, regulators, and Plaintiffs. The
4 Opioid Marketing Enterprise Members calculated and intentionally crafted the scheme and
5 common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In
6 designing and implementing the scheme, the Opioid Marketing Enterprise Members understood
7 and intended that those in the opioid distribution chain rely on the integrity of the pharmaceutical
8 companies and ostensibly neutral third parties to provide objective and scientific evidence
9 regarding the Opioid Marketing Enterprise Members' products.
10

11 1100. Opioid Marketing Enterprise Members' pattern of racketeering activity alleged
12 herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise,
13 the Opioid Marketing Enterprise Members are distinct from the Opioid Marketing Enterprise.
14

15 1101. The racketeering activities conducted by the Opioid Marketing Enterprise Members
16 amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive
17 consumers, prescribers, regulators, and Plaintiffs. Each separate use of the U.S. Mail and/or
18 interstate wire facilities employed by the Opioid Marketing Enterprise was related, had similar
19 intended purposes, involved similar participants and methods of execution, and had the same results
20 affecting the same victims, including consumers, prescribers, regulators, and Plaintiffs. The Opioid
21 Marketing Enterprise Members have engaged in the pattern of racketeering activity for the purpose
22 of conducting the ongoing business affairs of the Opioid Marketing Enterprise.
23

24 1102. Each of the Opioid Marketing Enterprise Members aided and abetted others in the
25 violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§
26 1341 and 1343 offenses.
27
28

1 1103. As described herein, the Opioid Marketing Enterprise Members engaged in a pattern
2 of related and continuous predicate acts for many years. The predicate acts constituted a variety of
3 unlawful activities, each conducted with the common purpose of obtaining significant money and
4 revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate
5 acts also had the same or similar results, participants, victims, and methods of commission. The
6 predicate acts were related and not isolated events.
7

8 1104. The Opioid Marketing Enterprise Members' violations of law and pattern of
9 racketeering activity directly and proximately caused Plaintiffs injury in their business and
10 property. The Opioid Marketing Enterprise Members' pattern of racketeering activity logically,
11 substantially, and foreseeably caused an opioid epidemic. The injuries of Plaintiff, as described
12 herein, were not unexpected, unforeseen, or independent. Rather, as Plaintiffs allege, the Opioid
13 Marketing Enterprise Members as a whole and, and Defendants and McKinsey in particular, knew
14 that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain,
15 or for any other use not approved by the FDA, and knew that opioids were highly addictive and
16 subject to abuse. Nevertheless, the Opioid Marketing Enterprise Members engaged in a scheme of
17 deception that utilized the mail and wires in order to carry out the Opioid Marketing Enterprise's
18 fraudulent scheme, thereby increasing sales of their opioid products.
19

20 1105. It was foreseeable and expected that the Opioid Marketing Enterprise Members
21 creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering
22 activities to carry out their fraudulent scheme would lead to a nationwide opioid epidemic,
23 including increased opioid addiction and overdose and the injuries that occurred as a result.
24

25 **The Enterprise Was Well Aware of Risks of Abuse Before It "Turbocharged" its Marketing**
26 **Scheme.**
27
28

1 1106. These devastating results were eminently foreseeable by the Opioid Marketing
2 Enterprise Members.

3 1107. When Purdue pleaded guilty in 2007, it was evident that Purdue's behavior and
4 excessive prescribing was directly linked to a drug addiction crisis that caused severe and extensive
5 damage to America. Purdue's methods included "using aggressive marketing tactics to convince
6 doctors to unnecessarily prescribe opioids – frivolous prescriptions that experts say helped fuel a
7 drug addiction crisis that has ravaged America for decades."⁷⁵²

9 1108. Defendants and McKinsey cannot deny knowledge regarding Purdue's 2007 guilty
10 plea. At that point, McKinsey knew that opioids were addictive. McKinsey knew that OxyContin
11 was being widely abused and causing harm to people and entities like Plaintiffs. And McKinsey
12 knew that Purdue had been fraudulently marketing OxyContin as less addictive, less subject to
13 abuse, and less likely to cause withdrawal. And yet, years later, in 2013, McKinsey orchestrated a
14 scheme with Defendants to continue to aggressively promote opioids despite knowledge that people
15 were still dying from overdoses.

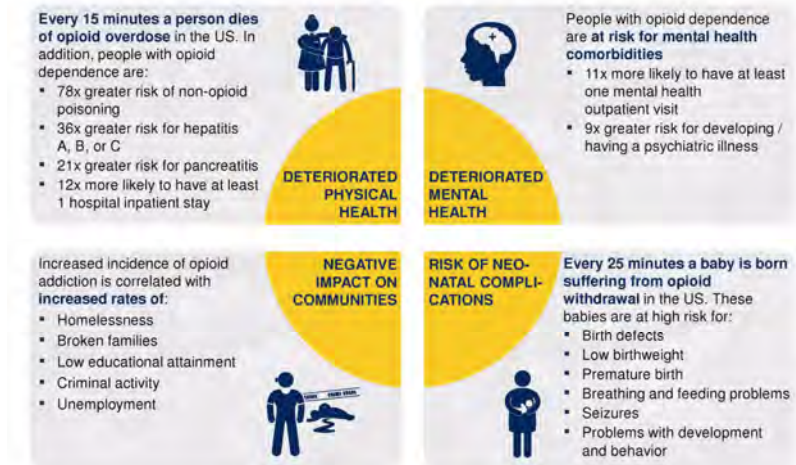
17 1109. Thus, Defendants and McKinsey continued to add fuel to this fire by persisting in
18 aggressively marketing to physicians and continuing to fuel the opioid crisis after Purdue's guilty
19 plea. It was foreseeable that continuing to do so would devastate American communities.

20 1110. [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]
27 [REDACTED]

⁷⁵² Jan Hoffman & Katie Benner, *Purdue Pharma Pleads Guilty to Criminal Charges for Opioid Sales*, N.Y. Times (updated Dec. 17, 2020), <https://www.nytimes.com/2020/10/21/health/purdue-opioids-criminal-charges.html>.

⁷⁵³ MCK-MDL2996-0070516, at 0070517.

More than two million Americans are addicted to opioids, which has devastating consequences for communities and individuals



SOURCE: NIH "A review of potential adverse effects of long-term opioid therapy: a practitioner's guide", Balon A et al. "Direct costs of opioid abuse in an insured population in the United States", White AG, Bimbaum HG, Marawa MN, et al. National Survey on Drug Use and Health, 2014. "Social Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States", Bimbaum et al. (2011)

McKinsey & Company 7

1111.

Opioid abuse has an estimated cost to society of ~\$80 billion (US)



¹ Estimated by prorating national estimate with overdose deaths in the State

SOURCE: "The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States", Florence et al. (2013)

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1 1112. Similarly, news stories across the nation reported additional consequences of wide
2 scale opioid addiction: needles littered around public property, posing costs to the governments and
3 danger to residents.⁷⁵⁴

4 1113. The foreseeability of the abuse and need for additional services that would be
5 required following the misleading marketing and increased prescribing and use of high dose opioids
6 is also evidenced by McKinsey's attempt to put a price tag on overdoses. McKinsey suggested
7 payment amounts for event-based contracts: \$6,000 to \$15,000 (paid to health insurers for increased
8 medical services). Indeed, McKinsey was well aware that increased prescriptions would lead to
9 overdoses and to an additional financial burden for social and health services.
10

11 1114. Defendants and McKinsey are liable for their successful efforts to increase
12 OxyContin sales after Purdue's 2007 guilty plea for misbranding the drug. Indeed, Defendants' and
13 McKinsey's focus on increasing opioid sales after Purdue's guilty was incendiary to escalating and
14 perpetuating the opioid epidemic by: (a) using data to specifically target high volume prescribers;
15 (b) persuading sales of higher doses of opioids; (c) tailoring marketing messages to conceal their
16 addictive principles; and (d) by reducing the training of sales representatives.
17

18 1115. In 2013, when the consent decree expired (which obligated Purdue to submit annual
19 compliance reports regarding its marketing), Defendants and McKinsey helped Purdue reengage in
20 its nefarious conduct of targeting and deceiving doctors about the abuse potential of opioids.
21

22 1116. After Purdue's guilty plea, Defendants and McKinsey identified physicians—that
23 had already been influenced by Purdue's misrepresentations and were thus already high
24 prescribers—as optimal targets for a massive marketing push to sell more OxyContin. Defendants
25 and McKinsey monitored the prescription behaviors of individual doctors and utilized the
26

27
28 ⁷⁵⁴ See, e.g., <https://www.bostonglobe.com/metro/regionals/south/2014/10/25/hypodermic-needles-litter-landscape-south-boston/pzgmgbyjYFCD967TePDyiM/story.html>

1 prescriber-level data and urged Purdue to allocate its time and resources to high prescribing
2 physicians.

3 1117. By November 2013, Defendants and McKinsey had obtained the physician-level
4 data it had previously requested and continued to study ways to sell additional OxyContin
5 prescriptions by refining and targeting the sales pitch to them.
6

7 1118. In 2013, Project Turbocharge began. McKinsey proposed Project Turbocharge, a
8 marketing strategy to increase opioids sales by hundreds of millions of dollars annually. With
9 Defendants and McKinsey's ongoing aid and assistance, Purdue trained its sales representatives to
10 operate using McKinsey's strategy for selling OxyContin. It is not coincidental to the Enterprise
11 scheme that as soon as the constraints associated with its guilty plea and consent agreement ended,
12 Defendants and McKinsey assisted Purdue in turbocharging sales.
13

14 1119. As Defendants and McKinsey were pushing hard to turbocharge and promote the
15 sale of opioids, McKinsey anticipated and expected that people would die from opioid overdoses.
16 It acknowledged this when, in 2017, it proposed that Purdue pay health insurers or other entities in
17 the distribution chain rebates "for every OxyContin overdose attributable to pills they sold."⁷⁵⁵

18 1120. Defendants and McKinsey cannot deny that it was not aware of the abuse and
19 overdose potential of opioids when it provided estimates for the future costs of overdose or opioid
20 use disorder events.
21

22 1121. Defendants and McKinsey and the other Opioid Marketing Enterprise Members
23 marketed a product, through intentionally deceptive means, that it knew would result in consumer
24 deaths and harm to Plaintiffs. This is not an attenuated causal chain. Rather, aggressively marketing
25 to high prescribing individuals, and training to not fully disclose the risk of abuse, were integral
26

27 ⁷⁵⁵ Walt Bogdanich & Michael Forsythe, *McKinsey Proposed Paying Pharmacy Companies Rebates for OxyContin*
28 *Overdoses*, N.Y. Times (updated Nov. 5, 2021), <https://www.nytimes.com/2020/11/27/business/mckinsey-purdue-oxycontin-opioids.html>

1 parts of the marketing scheme. Publicis even described itself as the “strategic backbone” of
2 McKinsey’s Project Turbocharge initiative. Deceptive messaging to targeted prescribers who were
3 likely to prescribe more pills in a dose with an anticipated abuse potential was part and parcel of
4 the scheme to defraud.

5
6 1122. As a result, Plaintiffs have shouldered the burden of these anticipated increased
7 services and harm to business and property that are inherently tied to opioid abuse and misuse, and
8 both the increased services and harms were reasonably and actually expected from increased
9 prescribing.

10 1123. The Enterprise’s goal was to increase opioid prescribing, and the Enterprise
11 Members knew that doing so would also result in the need for increased medical services. It was
12 also foreseeable that increased prescriptions would also result in increased costs to Plaintiffs and
13 communities throughout the United States.

14
15 1124. But for the increase in prescribed opioids, Plaintiffs would not have to expend
16 additional resources or suffered other harm to business and property as a result of harms associated
17 with opioid addiction. The Enterprise persisted in targeting prescribers to prescribe high doses of
18 opioids and knew that doing so would result in adverse health and social outcomes, including
19 overdoses, neo-natal complications, harm to communities like Plaintiffs, hazardous waste in
20 Plaintiff communities, as well as and increased expenditures on services to combat such ill effects.

21
22 **Plaintiffs’ Business and Property Have Been Damaged by the Enterprise’s RICO Violations.**

23 1125. The Opioid Marketing Enterprise’s misleading marketing and failure to prevent
24 prescription opioid diversion damaged Plaintiffs. In addition to medical services, the Opioid
25 Marketing Enterprise’s misconduct has contributed to a range of social problems, including
26 violence and delinquency. Adverse social outcomes include child neglect, family dysfunction,
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1 babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and
2 social despair. As a result, Plaintiffs are devoting more and more resources to the opioid epidemic.

3 1126. Notably, Plaintiffs have experienced vast harm to business and property directly,
4 proximately, and foreseeably caused by the racketeering enterprise. The full extent of each
5 Plaintiffs' damage cannot be fully captured in this pleading but can be fleshed out during the
6 bellwether process. Below are some discrete examples that demonstrate the common and typical
7 universal harm to Plaintiffs and the specific types of harm foreseeably caused by the Opioid
8 Marketing Enterprise.
9

10 1127. Specifically, the Opioid Marketing Enterprise Members' creation of, and then
11 participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to
12 carry out their fraudulent scheme has injured Plaintiffs in the form of substantial losses of money
13 and property that logically, directly and foreseeably arise from the opioid epidemic. The injuries to
14 Plaintiffs, as alleged throughout this Complaint, and expressly incorporated herein by reference,
15 include new, different, and increased expenditures by and losses to Plaintiffs, for example:
16

17 A. Hazardous waste in Plaintiffs' communities, including on Plaintiffs' real
18 property;

19 B. Costs for providing healthcare and medical care, additional therapeutic, and
20 prescription drug purchases, and other treatments for patients suffering from opioid-related
21 addiction or disease, including overdoses and deaths;

22 C. Costs of training first responders in the proper treatment of drug overdoses;

23 D. Costs associated with providing first responders with naloxone—an opioid
24 antagonist used to block the deadly effects of opioids in the context of overdose;

25 E. Costs associated with emergency responses by first responders to opioid
26 overdoses;
27
28

1 F. Costs for providing mental health services, treatment, counseling, rehabilitation
2 services, and social services to victims of the opioid epidemic and their families;

3 G. Costs associated with the injuries to the health and welfare of the residents who
4 reside in the jurisdiction of Plaintiffs caused by the opioid epidemic;

5 H. Costs associated with providing care for children whose parents suffer from
6 opioid-related disability or incapacitation; and

7 I. Losses caused by the diversion of revenue to address the opioid epidemic that
8 would otherwise have been used to provide other services.

9
10 1128. The injuries to Plaintiffs were directly and proximately caused by the Enterprise's
11 racketeering activities because they were the logical, substantial, and foreseeable cause of the
12 injuries to Plaintiffs. But for the opioid epidemic created by the Opioid Marketing Enterprise
13 Members through their Opioid Marketing Enterprise, Plaintiffs would not have lost money or
14 property, and the health and welfare of citizens would not have been harmed.

15
16 1129. Plaintiffs have been injured by the Enterprise's conduct, and such injury would not
17 have occurred but for the predicate acts which also constitute acts taken in furtherance of the
18 conspiracy pursuant to Section 1962(d). By working to expand the opioid market, fraudulently
19 concealing the abuse potential of opioids, targeting high volume prescribers, and deceiving
20 prescribers and the public in order to allow opioids to continue to remain on the market, the
21 Enterprise caused the expansion of opioid prescribing and caused a large number of people across
22 the United States, including in Plaintiffs' communities to become addicted to opioids, thus forcing
23 Plaintiffs to expend, time, money and resources to address the opioid epidemic that Defendants and
24 McKinsey and the Enterprise created through their conduct. Indeed, Defendants and McKinsey
25 intentionally deceived doctors and public health workers in order to continue to grow the opioid
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27
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1 market. The repeated fraudulent misstatements by Defendants and McKinsey contributed to an
2 explosion in the use of opioids across the country.

3 1130. Plaintiffs were direct victims of Defendants and McKinsey's misconduct. The
4 Enterprise displayed a wanton disregard for public health and safety by intentionally deceiving
5 doctors about the addiction potential of opioids and by marketing higher doses to physicians. The
6 harm created by Defendants and McKinsey required Plaintiffs to expend financial and other
7 resources to mitigate the health crisis of opioid misuse and addiction. The expansion of this market
8 was the goal of the Enterprise and was critical to its success. Therefore, the harm suffered by
9 Plaintiffs to their property forced them to expend resources beyond the ordinary costs of services
10 to combat the opioid epidemic, was directly foreseeable, and in fact, was an intentional result of
11 Defendants' and McKinsey's misconduct. Indeed, McKinsey anticipated overdose events and
12 actually estimated price premiums on these expected overdose events. Defendants and McKinsey
13 knew that the products it was marketing were highly addictive and could lead to deadly overdoses
14 yet continued to "turbocharge" sales by fraudulently pushing the product on doctors through its
15 deceptive marketing scheme.

16 1131. The creation and implementation of the marketing scheme that Defendants and
17 McKinsey developed and deployed through its Enterprise directly harmed Plaintiffs by imposing
18 costs on their businesses and properties. The harm caused by this scheme was an unnatural, human-
19 caused, profit-driven, and completely preventable disaster (had the Enterprise Members obeyed the
20 law). Thus, Plaintiffs' injuries are not solely the result of routine government expenses. Instead, as
21 a result of Defendants' and McKinsey's misconduct, Plaintiffs have been and will be forced to go
22 far beyond what a governmental entity might ordinarily be expected to pay to enforce laws and to
23 promote the general welfare in order to combat the opioid epidemic, whose primary origins were
24 in prescription opioids administered by prescribers whom Defendants and McKinsey targeted with
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1 their marketing scheme to increase sales. This includes providing new programs and new services
2 as a direct result and in direct response to Defendants' and McKinsey's misconduct. In addition,
3 Plaintiffs have suffered losses to their property as a direct result of the kind of inevitable
4 consequences of the drug addiction and criminal behavior that Defendants and McKinsey predicted.
5 As a result of the conduct of the Enterprise, Plaintiffs have incurred and will continue to incur costs
6 that far exceed the norm.
7

8 1132. The injuries to Plaintiffs were directly and proximately caused by these racketeering
9 activities because they were the logical, substantial, and foreseeable cause of the injuries to
10 Plaintiffs. But for the opioid epidemic the Opioid Marketing Enterprise Members created through
11 their Opioid Marketing Enterprise, Plaintiffs would not have lost money or property, and the health
12 and welfare of residents in Plaintiffs' jurisdictions would not have been harmed. Moreover,
13 Defendants and McKinsey's internal documents show that it actually did foresee many of the harms
14 that resulted from its conduct.
15

16 1133. There are no intervening acts or parties that could interrupt the causal chain between
17 Defendants' mail and wire fraud and Plaintiffs' injuries. Defendants, in furtherance of the
18 Enterprise's common purpose, caused to be made false and misleading statements directly to the
19 doctors (who consumers rely on to provide health advice) and the public. Doctors are not a break
20 in the causal chain. Instead, the Enterprise members as a whole, and Defendants and McKinsey in
21 particular, intentionally targeted doctors and sought to deceive them. That doctors were then
22 deceived and behaved as the Enterprise wanted, prescribing more and more opioids, was the
23 purpose of the scheme, not an intervening cause.
24

25 1134. The Enterprise's violations of 18 U.S.C. § 1962(c) have directly and proximately
26 caused injuries and damages to Plaintiffs, and Plaintiffs are entitled to bring this action for three
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28

1 times their actual damages, as well as for injunctive/equitable relief, costs and reasonable attorneys'
2 fees and costs pursuant to 18 U.S.C. § 1964(c).

3
4 **COUNT II:**
Negligence

5 1135. Plaintiff realleges and incorporates by reference the allegations set forth above.

6 1136. Negligence is established where the defendant owes the plaintiff a duty of care,
7 breaches that duty, and the plaintiff sustained an injury or loss proximately caused by the
8 defendant's breach.

9
10 1137. Defendants, through their work with Purdue and other opioid manufacturers, owed
11 a duty of care to the Plaintiff, pursuant to which it would not encourage the over-marketing and
12 over-prescribing of a controlled substance known at the time to be addictive and known at the time
13 to be a threat to public health.

14 1138. In violation of this duty, for decades Defendants devised and assisted Purdue, and
15 other opioid manufacturers, with implementing sales and marketing campaigns, including
16 prescriber targeting and salesforce incentive compensation structures that would dramatically
17 increase the amount of opioids prescribed and distributed in the Ponca Tribe.

18
19 1139. As a direct and proximate result of Defendants' negligent conduct, the Ponca Tribe
20 has suffered and will continue to suffer harm.

21 **COUNT III:**
22 **Gross Negligence**

23 1140. Plaintiff realleges and incorporates by reference the allegations set forth above.

24 1141. The oversupply of opioids and plague of addiction led to a widespread epidemic of
25 overdoses, illness, and death that claimed thousands of lives and cost many millions of dollars of
26 public spending—circumstances that constituted an imminent or clear and present danger
27 amounting to more than normal and usual peril.
28

1 1142. Defendants, through their work with Purdue and other opioid manufacturers, owed
2 a duty of care to the Plaintiff, pursuant to which they would not encourage the over-marketing and
3 over-prescribing of a controlled substance known at the time to be addictive and known at the time
4 to be a threat to public health.

5 1143. In violation of this duty, for decades Defendants devised and assisted Purdue and
6 other opioid manufacturers with implementing sales and marketing campaigns, including Purdue's
7 *Evolve to Excellence* campaign, that would dramatically increase the amount of opioids prescribed
8 and distributed to Plaintiff's citizens.

9 1144. As a direct and proximate result of Defendants' negligent conduct, Plaintiff has
10 suffered and will continue to suffer harm.

11
12
13 **COUNT IV:**
14 **Negligent Misrepresentation**

15 1145. Plaintiff realleges and incorporates by reference the allegations set forth above.

16 1146. Defendants, in the course of their business with Purdue and other opioid
17 manufacturers, failed to exercise reasonable care or competence by communicating false
18 information regarding Defendants' clients' opioids that Defendants knew would be used for
19 guidance by others in their business transactions, including the healthcare providers within Plaintiff
20 who were capable of prescribing Purdue's drugs.

21 1147. Plaintiff is one of a limited group of entities to whom Defendants knew Purdue and
22 other opioid manufacturers intended to supply with false information regarding opioids.

23 1148. Defendants knew that the false information was material to healthcare providers'
24 decision to prescribe opioids to patients. Defendants intended that such statements be relied upon
25 to encourage additional opioid prescriptions.

26
27 **COUNT V:**
28 **Public Nuisance**

1 1149. Plaintiff realleges and incorporates by reference the allegations set forth above.

2 1150. Oklahoma courts have long recognized that anything which interferes with public
3 health and promotes the spread of disease, bodily injury, and/or death, may be considered a public
4 nuisance, and that a use or interference with real property is not required. A public nuisance is one
5 which interferes with public health and welfare and creates an imminent risk of public harm.
6

7 1151. Defendants, though their work with Purdue Pharma and numerous other opioid
8 industry participants, created and continues to perpetuate and maintain a public nuisance to the
9 citizens of the Ponca Tribe through the massive manufacturing and distribution of millions of doses
10 of highly addictive, commonly abused prescription pain killers known as opioids.

11 1152. Defendants' conduct, including their misrepresentations and omissions regarding
12 opioids, as well as efforts designed to sell as many units of controlled substances as conceivably
13 possible, have fueled an opioid epidemic within the territorial limits of Plaintiff that constitutes a
14 public nuisance. Defendants and their opioid clients, to include Purdue, Endo, Janssen, and Teva,
15 knowingly exacerbated the opioid epidemic that affects entire municipalities, towns, and
16 communities.
17

18 1153. Defendants' conduct, including their misrepresentations and omissions regarding
19 opioids, as well as its efforts designed to sell as many units of controlled substances as conceivably
20 possible, constitute unlawful acts and/or omissions of duties, that annoy, injure, or endanger the
21 comfort, repose, health, and/or safety of others.
22

23 1154. As a direct and proximate result of the wrongful conduct set forth herein, Defendants
24 negligently, intentionally, and/or unreasonably interfered with the rights of the Plaintiff to be free
25 from unwanted injuries, addictions, diseases, sicknesses, overdoses, criminal actions, and have
26 caused ongoing damage, harm, and inconvenience to Plaintiff and its citizens.
27
28

1 1155. As a direct and proximate result, Plaintiff and its citizens have been exposed to the
2 risk of addiction to prescription opioids, have become addicted, and/or have suffered other adverse
3 consequences from their use of the addictive prescription opioids, and have been adversely affected
4 by the addiction and abuse of others in their communities from the highly addictive, prescription
5 pain medication.
6

7 1156. The annoyance, injury, and danger to the comfort, repose, health, and safety of
8 residents of Plaintiff includes, but is not limited to:

- 9 i. Drug overdose deaths in Oklahoma had already increased six-fold from 1999 to
10 2012. In 2010, overdose deaths surpassed car crash deaths in Oklahoma.
11 Defendants crafted a strategy that *tripled* OxyContin sales during that time;
- 12 ii. From 2004 to 2014, Oklahoma's unintentional poisoning death rate effectively
13 doubled, 8.2 deaths per 100,000 individuals to 16.3 per 100,000. Prescription
14 opioids contributed to the majority of those deaths. The following year,
15 McKinsey developed and with Defendants implemented "Project Turbocharge,"
16 which was adopted as the national sales theme for the following year, under the
17 rubric of "Evolve to Excellence";
- 18 iii. In 2014, during the first year of "Evolve to Excellence," Oklahoma suffered in
19 excess of 600 deaths attributable to opioid overdoses. By 2018, the number
20 almost doubled, to 1,132.
- 21 iv. Prescription opioid addiction often leads to illicit opioid use and addiction;
- 22 v. According to the Centers for Disease Control, past misuse of prescription
23 opioids is the strongest risk factor for heroin initiation and use;
- 24 vi. Oklahoma hospitals are reporting increasing numbers of newborns testing
25 positive for prescription medications; and
26
27
28

vii. Defendants crafted deceptive marketing strategies that were prepared for Purdue, purchased by Purdue, and implemented by Purdue with Defendants' ongoing assistance. These strategies enflamed, purposefully, an opioid abuse and addiction epidemic that has caused the Tribe, its businesses, communities and citizens to bear enormous social and economic costs including increased health care, criminal justice, and lost work productivity expenses, among others.

1157. Defendants' conduct annoys, injures, and/or endangers the comfort, repose, health, and safety of others. In addition, Defendants' conduct caused and continues to cause harm to Plaintiff and its citizens.

1158. Plaintiff seeks to abate the public nuisance Defendants enflamed and all necessary relief to abate such public nuisance.

COUNT VI. Fraud (Actual and Constructive) and Deceit

1159. Plaintiff realleges and incorporates by reference the allegations set forth above.

1160. Defendants made and caused to be made false representations to healthcare providers working in Plaintiff's territory, and/or omitted material facts, regarding the risks, efficacy, and medical necessity of opioids, generally, and Defendants' clients' opioids, specifically. Defendants knew these representations were false, made recklessly without knowledge of the truth, and/or had no reasonable ground for believing such assertions. Specifically, Defendants knowingly and/or recklessly:

- i. Downplayed the substantial risks of addiction and other side-effects of opioids, including crafting its clients' opioid sales and marketing strategies;
- ii. Overstated the efficacy of opioids generally, including making false statements regarding the effectiveness of the drugs for treating specific subsets of the patient

1 population (i.e., those with osteoarthritis) and their ability to improve patient
2 function; and

- 3 iii. Misrepresented the medical usefulness and necessity of opioids, generally, and
4 Purdue's and other opioid manufacturer's opioids specifically, including
5 affirmatively marketing their drugs for off label uses (i.e., fibromyalgia
6 osteoarthritis) without solicitation and not in response to questions from
7 healthcare providers.
8

9 1161. Defendants and their clients' misrepresentations and omissions deceived others,
10 violated public confidence, and/or injured public interests. Defendants, having chosen to craft the
11 marketing plans used by Purdue and other opioid manufacturers to make misrepresentations to
12 healthcare providers regarding their opioids, was under a duty to disclose the whole truth, and not
13 disclose partial and misleading truths.
14

15 1162. Defendants intended healthcare providers to rely upon the false representations
16 regarding the risks, efficacy, and medical necessity of opioids, generally, and Defendants' clients'
17 opioids, specifically, to increase the number of opioid prescriptions made by healthcare providers.
18

19 1163. Healthcare providers working in Plaintiff's territory did in fact rely on the false
20 representations made in the course of numerous opioid sales and marketing plans created by
21 Defendants and implemented with Defendants' ongoing assistance to its clients.

22 1164. Plaintiff seeks to recover all damages caused by Defendants fraudulent
23 representations and omissions.

24 1165. Defendants acted with knowledge and willful intent, with reckless disregard for the
25 rights of others, and/or intentionally and with malice towards others. As such, Plaintiff seeks to
26 recover punitive damages against Defendants.
27
28

**COUNT VII:
Civil Conspiracy**

1166. Plaintiff realleges and incorporates by reference the allegations set forth above.

1167. Defendants and their opioid manufacturer clients, working together for decades, agreed to commit numerous unlawful acts relating to the sale and marketing of their opioid products. Defendants and their opioid clients also agreed to use unlawful means to commit lawful acts as part of these sales and marketing efforts.

1168. Defendants and their opioid clients agreed to pursue the unlawful act of knowingly misrepresenting the addictive nature of opioids in marketing their opioids to health care providers within Plaintiff's territory.

1169. Defendants and Purdue deployed the unlawful means of evading Purdue's reporting and compliance obligations to the Inspector General of the United States Department of Health and Human Services for the five years Purdue was subject to a Corporate Integrity Agreement after it pled guilty in 2007 to criminal misbranding.

1170. Defendants and their opioid clients discussed herein conspired to violate the Oklahoma Consumer Protection Act, 15 OK Stat § 15-753 *et. seq.* Defendants and their clients engaged in deceptive trade practices including, making and causing to be made misrepresentations and omissions in marketing of opioids in general, and Defendants' clients' opioids, specifically, that deceived or could reasonably be expected to deceive or mislead consumers.

1171. Defendants and their numerous opioid clients engaged in unfair trade practices, including, intentionally downplaying the risks, overstating the benefits, and misrepresenting the medical necessity of opioids, generally, and Defendants' clients' opioids, specifically, including for off-label uses. These practices offend established public policy and are immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.

1 1172. Defendants knowingly made or caused to be made false or misleading
2 representations as to the characteristics, ingredients, uses, and benefits of opioids, generally, and
3 Defendants' clients' opioids, specifically, by downplaying the risks of addiction and abuse,
4 overstating the efficacy, and misrepresenting the medical necessity of opioids, generally, and
5 Defendants' clients' opioids, specifically.

6
7 1173. Defendants and their numerous opioid clients agreed to deploy unlawful sales and
8 marketing tactics to achieve the lawful purpose of maximizing ROI for Defendants' opioid clients.

9 1174. As a consequence, Defendants are jointly and severally liable with its opioid clients
10 for the salesforce optimization and sales and marketing practices used to promote ZS' clients'
11 opioid products, including Purdue's OxyContin, Teva's Fentora, Endo's Opana, Janssen's Nucynta,
12 and others.

13
14 1175. Plaintiff was damaged as a result of the unlawful acts Defendants conspired with its
15 clients to commit.

16 **COUNTY VIII:**
17 **Civil Aiding and Abetting**

18 1176. Plaintiff realleges and incorporates by reference the allegations set forth above.

19 1177. Defendants gave substantial assistance and encouragement to Purdue and their other
20 opioid clients regarding conduct Defendants knew to be tortious and/or in violation of a duty owed
21 by clients to third persons, including Plaintiff.

22
23 1178. Plaintiff was damaged as a result of the specific conduct that Defendants encouraged
24 and substantially assisted.

25
26 **COUNT IX**
27 **Unjust Enrichment**

28 1179. Plaintiff realleges and incorporates by reference the allegations set forth above.

1180. Unjust enrichment is established where the plaintiff alleges: (a) a benefit conferred upon the defendant by the plaintiff; (b) an appreciation or knowledge by the defendant of the benefit; and (c) the acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without the payment of its value.

1181. Defendants were compensated for their years of work increasing opioid sales and maximizing profits for its opioid clients.

1182. The compensation Defendants accepted from opioid manufacturers for maximizing sales of their deadly opioid products, by misrepresenting their addictiveness, constitutes money in the possession of Defendants that, in equity and good conscience, Defendants ought not be allowed to retain.

VII. JURY DEMAND

Plaintiff, on behalf of itself and all others similarly situated, requests a trial by jury on all issues so triable.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and all others similarly situated, respectfully prays that this Court grant the following relief:

- i. Enter Judgment in favor of Plaintiff, on behalf of itself and all others similarly situated, against Defendants awarding Plaintiff its actual damages caused by the opioid epidemic, including but not limited to (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths (2) costs for providing treatment, counseling and rehabilitation services, (3) costs for providing treatment of infants born with opioid-related medical conditions, (4) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation, (5) costs

1 associated with law enforcement and public safety relating to the opioid epidemic, and
2 (6) costs associated with drug court and other resources expended through the judicial
3 system;

4 ii. Order that Defendants compensate Plaintiff, on behalf of itself and all others similarly
5 situated, for past and future costs to abate the ongoing public nuisance caused by the
6 opioid epidemic;

7
8 iii. Order Defendants to fund an “abatement fund” for the purposes of abating the opioid
9 public nuisance;

10 iv. Enter judgment against Defendants requiring Defendants to pay punitive damages;

11 v. Enter judgment against Defendants awarding Plaintiff its reasonable attorneys’ fees, all
12 costs and expenses, pre-judgment and post-judgment interest; and

13
14 vi. All other such and further relief as this Court may deem just and proper.
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16
17

18 Dated: October 31, 2022

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